Pharmacy-Based Immunization Delivery Certificate Training Program

PowerPoint Presentation

April 2013

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

Acknowledgements

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Financial Disclosures

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  - Spouse is an employee of Merck

All other individuals in a position to impact the content of this activity declare no conflicts of interest or financial interests in any product or service mentioned, including grants, employment, gifts, stock holdings, and honoraria.

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Learning Objectives

- Upon completion of this application-based activity, the participant will be able to—
  - Identify opportunities for pharmacists to become involved in immunization delivery
  - Describe how vaccines evoke an immune response and provide immunity
  - Identify the vaccines available on the U.S. market for each vaccine-preventable disease and classify each vaccine as live attenuated or inactivated
  - Evaluate a patient's medical and immunization history and determine whether the patient falls into the target groups for each vaccine based on the Advisory Committee for Immunization Practices recommendations

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Learning Objectives

- *Upon completion of this application-based activity, the participant will be able to—*
  - *Review a patient case and determine patient-specific vaccine recommendations based on the appropriate immunization schedule*
  - *Discuss the legal, regulatory, and liability issues involved with pharmacy-based immunization programs*
  - *Recognize the signs and symptoms of adverse reactions that can occur after vaccination*
  - *Describe the emergency procedures for management of patients with adverse reactions to vaccination*
  - *List the steps for appropriate intranasal administration of the live attenuated influenza vaccine*
  - *Demonstrate appropriate intramuscular and subcutaneous injection technique for adult immunization*

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The Importance of Vaccines

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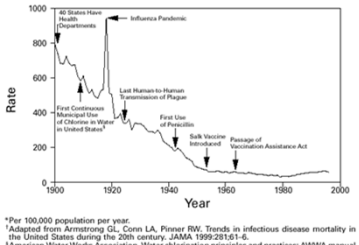
Achievements in Public Health

Vaccine Development

1798 Smallpox
1881 Anthrax
1885 Rabies
1896 Cholera, Typhoid
1897 Plague
1923 Diphtheria
1926 Pertussis
1927 Tetanus
1936 Influenza
1955 IPV
1963 Trivalent OPV, Measles
1969 Rubella
1971 MMR
1982 Hepatitis B
1987 Hib
1995 Varicella, Hepatitis A
2005 Tdap
2006 Rotavirus, HPV, Zoster

FIGURE 1. Crude death rate* for infectious diseases — United States, 1900–1996†



*Per 100,000 population per year.
†Adapted from Armstrong GL, Conn LA, Pinner RW. Trends in infectious disease mortality in the United States during the 20th century. JAMA 1999;281:61–6.
§American Water Works Association. Water chlorination principles and practices: AWWA manual M20. Denver, Colorado: American Water Works Association, 1973.

CDC. MMWR. 1999;48(29):621-9.

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Vaccine-Preventable Diseases in the 21st Century

Disease	Max. Cases	Year	Cases 2006	Cases 2007	Cases 2008	Cases 2009	Cases 2010	Cases 2011	Cases 2012
Diphtheria	206,939	1921	0	0	0	0	0	0	0
Hib	~20,000	1980's	29	22	30	35	23	14	21
Measles	894,134	1941	55	43	140	71	63	220	55
Mumps	152,209	1968	6,584	800	454	1991	2612	404	199
Pertussis	265,209	1934	15,632	10,454	10,007	16,858	27,550	18,719	41,880
Paralytic Poliomyelitis	21,269	1952	0	1	0	0	0	0	0
Rubella	2.5 Million	1964-1965	11	12	17	3	5	4	8
CRS	~30,000		1	0	0	2	0	0	2
Tetanus	601	1948	41	20	15	18	26	36	36
Varicella	221,983	1984	32,242	40,146	30,386	20,480	15,427	14,513	11,477

Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed.; JAMA. 2007;298:2155-263.; MMWR Morb Mortal Wkly Rep. 2013;61(51 and 52)

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Shortfalls in Vaccine Delivery and Opportunities for Pharmacists

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Impact of Influenza and Pneumococcal Disease

- *8th leading cause of death in the United States in 2009*
- *Missed opportunities*
  - *Of those patients who die from influenza*
    - *1/2 to 2/3 were hospitalized in the previous 5 years but were not vaccinated*
    - *2/3 saw physicians as outpatients in previous year but were not vaccinated*

National Center for Health Statistics. National Vital Statistics Reports. Deaths: leading causes for 2010.

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Vaccination Rates in Adults 2011

Vaccine (Target Group)	Vaccination Rate (%)
Influenza (50–64 years)	47.2
Influenza (≥65 y/o)	64.9
Influenza (health care personnel (HCP))	66.9
Pneumococcal (≥65 y/o)	64.5
Pneumococcal (19-64 y/o high risk)	20.1
Tdap in past 6 years (19–49 y/o)	12.5
Tdap (HCP) 2005-2011	26.8
Hepatitis B (≥ 3 doses 19-49 y/o	35.9
Hepatitis B (HCP)	63.2
HPV Females (≥1 dose)	21.5
Zoster vaccine (≥60 y/o)	15.8

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National Health Interview Survey –2011 (http://www.cdc.gov/mmwr/pdf/wk/mm62e0129.pdf)
National Immunization Survey 2011-2012
http://www.cdc.gov/MMWR/preview/mmwrhtml/mm6138a1.htm

Vaccination Rates Among Adults by Race/Ethnicity

Race/Ethnicity	Influenza (≥18 years) (%)	Pneumococcal (≥65 years) (%)
Black	32.7	47.6
Hispanic	29.4	43.1
White	41.9	66.5

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National Health Interview Survey 2011.

Outbreaks of Disease

- Measles Outbreak (2011)[1]
  - 222 cases reported
  - Five times the number of cases in 2007
  - 28,000 cases in Europe
- Mumps Outbreak (2011)[2]
  - 29 Mumps cases on University campus in California
  - Source – unvaccinated student – all cases linked
  - 22 (76%) vaccinated with 2 doses MMR
    - 2 with 3 doses, 2 with 1 dose, and 2 unknown
- Pertussis Epidemic[3]
  - 41,880 cases reported in 2012
    - 18 related deaths
    - 4,783 in Washington State (965 in 2011)
  - 18,719 cases total reported in U.S. in 2011
  - 27,555 in 2010

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1. Measles. www.cdc.gov/measles
2. MMWR Morb Mortal Wkly Rep. 2012;61:986-989
3. CDC Pertussis Report (www.cdc.gov/pertussis)

Patients Slipping Through the Cracks

In the patient → physician → pharmacist → patient cycle, the physician has the first chance to immunize the patient.

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Roles of Pharmacists in Immunization Advocacy

- *Pharmacist as educator*
  - *Serving as an advocate and motivating patients*
- *Pharmacist as facilitator*
  - *Hosting others who vaccinate*
- *Pharmacist as immunizer*
  - *Administering vaccinations*

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1996 APhA House of Delegates, Nashville, TN

Pharmaceutical Care and Medication Therapy Management (MTM)

- *Pharmaceutical care is the provision of drug therapy to achieve outcomes that improve a patient's quality of life—these outcomes are:*[1]
  - *Cure of a disease*
  - *Elimination or reduction of symptoms*
  - *Arresting or slowing of a disease process*
  - *Preventing a disease or symptoms*
- *MTM services should include an assessment and evaluation of the patient's complete medication therapy regimen*[2]

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1. Hepler CD, Strand LM. Am J Hosp Pharm. 1990;47:533-43. 2. APhA, NACDS Foundation. Medication Therapy Management in Pharmacy Practice. Core Elements of an MTM Service Model. Version 2.0. March 2008.

"Prevent All the Disease You Can...

. . . THEN TREAT THE REST."

John D. Grabenstein, 1994

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How Do Vaccines Prevent Disease?

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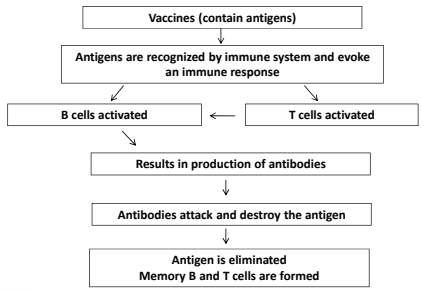
Vaccines and the Immune Response



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How Do Memory B and T Cells Provide Immunity?

- Memory B and T cells circulate through the body monitoring for the antigen
- If the antigen is recognized, memory cells—
  - Activate the immune response immediately
  - Produce antibodies quickly
  - Prevent disease from occurring because the antigen is eliminated rapidly

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Vaccine Types

- Live attenuated vaccines
  - Made from viruses or bacteria
  - Must replicate to work
    - Replication mimics natural infection, which stimulates immune response
- Inactivated vaccines
  - Made from viruses or bacteria
    - Various fractions: Subvirions, subunits, polysaccharides, toxoids, recombinant antigens
  - Do not replicate because they are killed
    - Antigen load stimulates immune response

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Testing Your Knowledge

Live

- Herpes zoster
- Live attenuated influenza
- Measles, mumps, rubella
- Oral typhoid capsules
- Rotavirus
- Varicella
- Yellow fever

Inactivated

- Diphtheria, tetanus, pertussis
- Haemophilus influenzae type B
- Hepatitis A
- Hepatitis B
- Human papillomavirus
- Inactivated poliovirus
- Meningococcal
- Pneumococcal
- Rabies
- Trivalent inactivated influenza
- Typhoid Vi injection

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Differences to Consider for Live and Inactivated Vaccines

- *Storage*
- *Timing of doses*
- *Duration of protection*
- *Adverse effects*
- *Contraindications and precautions*

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Polysaccharide vs. Conjugate Polysaccharide Vaccines

Polysaccharide

- *Stimulate T-cell independent immunity*
  - *Stimulate B cells without assistance of T helper cells*
  - *Short-lived immunity*
  - *No booster effect*
  - *Not consistently immunogenic in children <2 y/o*

Conjugate Polysaccharide

- *Stimulate T-cell dependent immunity*
  - *T helper cells involved*
  - *Produce immunologic memory*
  - *Result in booster effect upon subsequent exposure*
  - *Increased immunogenicity in children <2 y/o*

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Vaccine-Preventable Diseases

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Influenza

Photograph courtesy of Centers for Disease Control and Prevention

- Highly infectious viral illness
- Spread by respiratory route
- Symptoms
  - Fever
  - Cough
  - Sore throat
  - Runny or stuffy nose
  - Body aches
  - Headache
  - Chills
  - Fatigue

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Complications of Influenza

- Pneumonia
  - Most frequent complication of influenza
- Can exacerbate underlying medical conditions
- Can cause myocarditis
- Associated with Reye's syndrome
- Hospitalizations and deaths
  - From 1976 to 2007, the estimated number of annual influenza-related deaths from respiratory and circulatory causes ranged from a low of 3,349 to a high of 48,614

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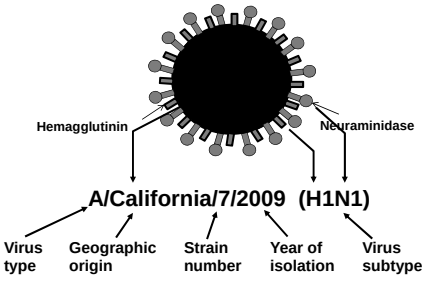
MMWR Morb Mortal Wkly Rep. 2010;59(33):1057-1062.

Influenza Virus



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CDC. Prevention and control of influenza with vaccines: recommendations of the ACIP, 2011. MMWR. 2011.60:1128-1132

Antigenic Drift and Shift

Antigenic Drift

- *Types A and B*
  - *Gradual change in proteins because of mutations, substitutions, and deletions*
  - *Adaptation to human antibodies*
  - *Occurs yearly*
  - *Responsible for epidemics*

Antigenic Shift

- *Type A only*
  - *Drastic change in hemagglutinin or neuraminidase*
  - *Yields a new strain of influenza*
  - *Occurs less frequently*
  - *Responsible for pandemics*

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Influenza Pandemic History

- *Spanish flu (H1N1) 1918–1919*
  - *50 million deaths worldwide*
    - *675,000 deaths in the United States*
- *Asian flu (H2N2) 1957–1958*
  - *70,000 deaths in the United States*
- *Hong Kong flu (H3N2) 1968–1969*
  - *34,000 deaths in the United States*
- *Reappearance of A(H1N1) 1976 (scare)*
- *Russian Flu (H1N1) 1977-1978 – Only epidemic level*
- *2009 H1N1 influenza 2009–2010*
  - *Between 43 million and 89 million cases of H1N1 influenza*
  - *Between 195,000 and 403,000 H1N1-related hospitalizations*
  - *Between 8,870 and 18,300 H1N1-related deaths*

www.flu.gov/general/historicaloverview.html

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Recent Influenza Activity in the United States

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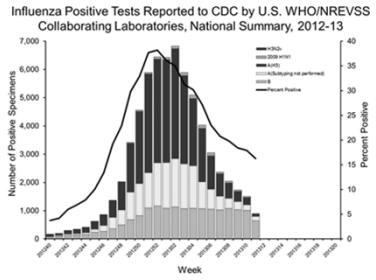
Influenza Activity in United States 2012-2013 season



Reports Through March 16, 2013

www.cdc.gov/flu/weekly

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Prevention of Influenza

- *The most effective strategy for preventing influenza and its complications is annual vaccination*
- *Influenza vaccination should be administered to all persons aged ≥6 months who do not have contraindications to the vaccine*

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2013–2014 Influenza Vaccine

- *Influenza vaccine contains:*
  - *A/California/7/2009 (H1N1)–like virus*
  - *A/Texas/50/2012 (H3N2)–like virus*
  - *B/Massachusetts/2/2012–like virus*
    - *Yamagata lineage*
  - *Note: A(H3N2) and B differ from 2012-2013 season*
- *Quadrivalent Addition*
  - *B/Brisbane/60/2008-like virus*
    - *Victoria lineage*

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Seasonal Influenza Vaccines

Vaccine (manufacturer)*	Approved Age Indications
Inactivated Influenza Vaccine	
Fluzone (sanofi pasteur)	*≥6 months*
Fluvirin (Novartis)	*≥4 years*
Fluarix (GSK)	*≥3 years*
FluLaval (GSK)	*≥18 years*
Afluria (CSL Biotherapies)	*≥9 years*
Agriflu (Novartis)	*≥18 years*
Fluzone High-Dose (sanofi pasteur)	*≥65 years*
Fluzone Intradermal (sanofi pasteur)	*18-64 years*
Flucelvax (Novartis) – cell cultured (not eggs)	*≥18 years*
Flublok (Protein Sciences Corp) -recombinant	*18-49 years*
Live Attenuated Influenza Vaccine	
FluMist (MedImmune)	*2 years to 49 years*

*Table lists the influenza vaccines that will be available during the 2013-2014 influenza season. Vaccine availability is subject to change. Pharmacists should always verify product availability and age indications for each vaccine.

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High-Dose and Intradermal Influenza Vaccine (sanofi pasteur)

- *Fluzone High-Dose*
  - *4 times the antigen dose*
  - *Higher immune response (antibody levels)*
  - *Indicated ages ≥ 65 years*
- *Fluzone Intradermal*
  - *Uses a novel microinjection system to deposit vaccine antigen into the dermal layer of the skin*
  - *Uses an ultrafine needle that is 90% shorter than the typical needle used for intramuscular injection*
  - *Indicated for adults ages 18–64 years*
- *ACIP makes no preference for any flu vaccine*

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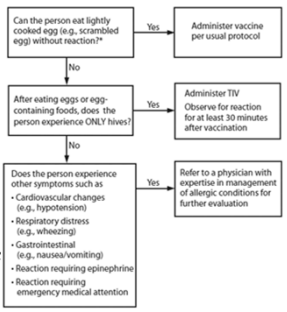
Eggs and Influenza Vaccine

- *Most flu vaccines made in embryonated hen eggs*
- *Risk of allergy much lower than risk of influenza*
- *New recommendations (ACIP 2011)*
  - *Not a contraindication (only a precaution)*
  - *Use IIV, not LAIV*
  - *Have ability to resuscitate and observe for 30 minutes*



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Differences Between IIV and LAIV

	IIV	LAIV
Type of vaccine	Inactivated	Live attenuated
Route of administration	IM injection Intradermal (ID) injection	Intranasal spray
Number of Antigens	3 or 4	4
Approved age	Persons aged ≥6 months*	Persons aged 2–49 years
Can be administered to persons with chronic medical conditions	Yes	No
Can be administered to close contacts of immunosuppressed patients requiring a protected environment	Yes	No

*Pharmacists should verify the approved age indication for each individual vaccine.

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Common Myth About Influenza Vaccine

- Myth: Influenza vaccine can cause influenza
  - Fact: IIV cannot cause influenza illness because it is an inactivated vaccine
  - Fact: LAIV cannot cause influenza illness because it cannot replicate in the temperature of the lower respiratory tract

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LAIV Warnings and Precautions

- Must carefully screen for:
  - Current health status
  - Presence of chronic medical conditions
  - Close contact with severely immunocompromised patients
  - Pregnancy
    - Pregnant patients should not receive LAIV; they should receive IIV
    - Pregnant providers may administer LAIV

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Frequently Asked Question

- *Can a patient transmit the live attenuated influenza vaccine virus to another person?*
  - *While shedding of vaccine virus occurs following administration of LAIV, transmission to another person is rare*

Would You Recommend IIV or LAIV?

	IIV or LAIV
Healthy community pharmacist (32 y/o) administering influenza vaccine to the general public; no contraindications	IIV or LAIV
38 y/o patient with diabetes	IIV
2 y/o healthy child with no contraindications	IIV or LAIV
Pregnant patient with no contraindications	IIV
67 y/o patient who needs pneumococcal and zoster vaccines simultaneously with influenza vaccine	IIV

Dosing of Influenza Vaccine

Patient Age	Number of Doses	Dose
IIV		
6 months to 35 months	*1 or 2**	*0.25 mL IM*
3 years to <9 years	*1 or 2**	*0.5 mL IM*
≥9 years	*1*	*0.5 mL IM*
LAIV		
2 years to 49 years	*1 or 2**	*1 spray in each nostril*

**The ACIP recommends two doses of age-appropriate influenza vaccine administered ≥4 weeks apart for children aged 6 months to 8 years who are receiving influenza vaccine for the first time.*

Timing for Influenza Vaccine Administration

- When should you offer influenza vaccines in your pharmacy?
  - Start whenever the vaccine becomes available
  - If possible, offer the vaccine any time you encounter a patient who is eligible to receive the vaccine
  - If there is a shortage, follow prioritization guidelines for vaccine administration
- How long should you provide influenza vaccine?
  - Continue vaccinating until your supply is gone, even after influenza activity is documented in your community

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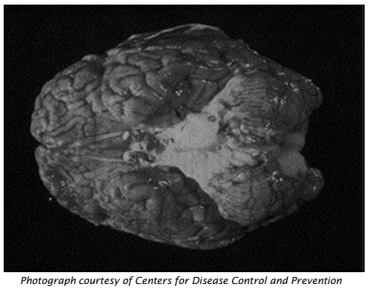
Pneumonia, Meningitis, or Sepsis



Photograph courtesy of Centers for Disease Control and Prevention

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Pneumococcal Disease

- Caused by Streptococcus pneumoniae
- A leading cause of vaccine-preventable illness and death in the United States
- A frequent cause of secondary bacterial pneumonia following influenza illness
- Identified as an important complication in severe and fatal cases of 2009 H1N1 influenza infection
- Threat exists year-round, not just in winter
- Antibiotic resistance is common

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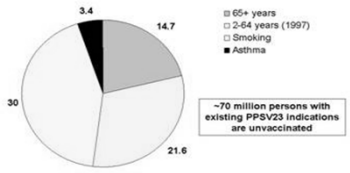
Pneumococcal Polysaccharide Vaccine 23-valent (PPSV)

- *Pneumovax 23 (Merck)*
  - *Protects against 85%–90% of serotypes known to cause invasive disease*
  - *Reduces the risk of invasive disease by 60%–70%*
  - *More efficacious against bacteremia than pneumonia*
  - *Not adequately effective in people <2 y/o*

Patients at Risk

Number (millions) of unvaccinated persons among those with existing ACIP indications for PPSV23



Source: National Health Interview Survey, 2007

Graph courtesy of Centers for Disease Control and Prevention

Applying Your Knowledge to Practice

- *What are the target groups for vaccination with pneumococcal polysaccharide vaccine?*
  - *All people ≥65 years old*
  - *People age 19–64 years old who smoke cigarettes*
  - *People age 19–64 years old who have asthma*
  - *People ≥2 years old with chronic illness*
- *As a pharmacist, how can you identify patients in need of a pneumococcal polysaccharide vaccine?*
  - *By their age or by the medications they take for their chronic illness*
- *What is the dose and route of administration for PPSV?*
  - *0.5 mL IM (or SC)*

Summary: Revaccination With PPSV

- Revaccinate these people:
  - People ≥65 y/o who received initial dose(s) ≥5 years ago and when <65 y/o
  - People 2–64 y/o at highest risk of death (e.g., asplenia, immunosuppression, sickle cell disease), who received initial dose ≥5 years ago

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Testing Your Knowledge

Which of the following patients would be an appropriate candidate for revaccination with PPSV?

A. 67 y/o patient (received first dose of PPSV at 62 y/o)
B. 77 y/o patient (received first dose of PPSV at 65 y/o)
C. 63 y/o patient (received first dose of PPSV at 60 y/o)
D. 78 y/o patient (received first dose of PPSV at 70 y/o)

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Pneumococcal Conjugate Vaccine 13-valent (PCV13)

- Prevnar 13 (Wyeth/Pfizer)
  - Replaces PCV7
- Indicated for the active immunization of children ages 6 weeks to 5 years old
  - For the prevention of invasive disease caused by 13 Streptococcus pneumoniae serotypes
  - For the prevention of otitis media caused by 7 Streptococcus pneumoniae serotypes
- FDA approved for adults aged 50 years and older (Not ACIP recommended for routine use)
- Dose and route: 0.5 mL IM

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Pneumococcal Conjugate Vaccine 13-valent (PCV13)

- Target groups for vaccination
  - Infants and children
- Routine schedule: 2, 4, 6, 12–15 months
  - Any PCV series begun with PCV7 should be completed with PCV13
- Administer a single supplemental dose of PCV13 for:
  - Children aged 14–59 months who have received an age-appropriate series of PCV7
  - Children aged 60–71 months with underlying medical conditions who have received an age-appropriate series of PCV7

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PCV13 for Adults

- FDA Approved adults ≥50 years
  - Approval based upon serology
- ACIP
  - No recommendations for routine use in all adults at this time
    - Not enough data to evaluate
    - Studies currently ongoing.
  - Recommended for immunocompromising conditions, functional or anatomical asplenia, CSF leaks, or cochlear implants.

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New ACIP Recommendation for Immunocompromised

Two dosage schedules are recommended:

1. PPSV naïve patients

   PCV13 ⟶ PPSV23 ⟶ PPSV23 + PPSV23(age 65 years or older)
   8 weeks ≥5 years

2. Previously vaccinated with PPSV23

   a. PPSV23 ⟶ (≥5 years) PCV13 ⟶ PPSV23 + PPSV23 (age 65 or older)
   ≥1 year ≥8 weeks

   b. PPSV23 ⟶ PPSV23 ⟶ PCV13 + PPSV23 (age 65 or older)
   ≥5 years ≥1 year

   c. PPSV23 ⟶ PPSV23 + PPSV23 (at age 65 or older) ⟶ PCV13
   ≥5 years ≥1 year

It is possible that these patients could receive three doses of PPSV23 in their lifetime.

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Pneumococcal Vaccines: Recap of Indications

- PPSV23
  - Everyone ≥65 y/o
  - People 19–64 y/o who have asthma
  - People 19–64 y/o who are smokers
  - People 2–64 y/o who have chronic illness
- PCV13
  - Routine vaccination for all infants <2 y/o
  - 1 dose for all children aged 14–59 months who received PCV7
  - 1 dose for all children aged 60–71 months with underlying medical conditions who received PCV7
  - 1 dose for adults with immunocompromising conditions

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What Is This Infectious Disease?

Photographs courtesy of CDC Public Health Image Library

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Varicella

- Varicella zoster virus
  - Primary infection: varicella (i.e., chickenpox)
- Transmission
  - Via respiratory droplets or contact with lesions
- Very contagious
- Complications
  - Secondary bacterial infection
  - Encephalitis
  - Pneumonia
  - Hospitalization
  - Death

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Varicella Vaccine

- Varivax (Merck)
  - Live attenuated virus vaccine
- What are the target groups for varicella vaccination?
  - Children 12–18 months old and 4–6 y/o
  - All susceptible individuals (>12 months old) with no evidence of immunity

Frequently Asked Questions

- Should a patient who provides a verbal history of chickenpox be considered immune to varicella?
  - No, a verbal history provided by the patient is no longer considered sufficient evidence of immunity
- How can a patient demonstrate evidence of immunity?
  - Documentation of age-appropriate vaccination
  - Laboratory confirmation after natural infection
  - Birth in the United States before 1980
  - Diagnosis or verification of history of varicella or herpes zoster by health care provider

Varicella Vaccine Dosing

- Patients should receive a total of two doses
  - Routine schedule for children
    - First dose at 12–15 months old
    - Second dose at 4–6 y/o
  - Schedule for susceptible adolescents (>13 y/o) and adults
    - Two doses separated by at least 4 weeks
- Dose and route: 0.5 mL SC

Testing Your Knowledge

- *Why is the first dose of varicella vaccine not given before a child's first birthday?*
  - *This is a live vaccine that must replicate to stimulate an immune response*
  - *Circulating maternal antibodies that can be present in a child for up to the first year of life can interfere with the vaccine*

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Applying Your Knowledge to Practice

- *Johnny, an 8 y/o boy, received the varicella vaccine. After the vaccination, he developed a small rash consisting of about 30 lesions. Johnny's mother calls the pharmacy because she is concerned about the rash.*
- *What do you tell Johnny's mother?*

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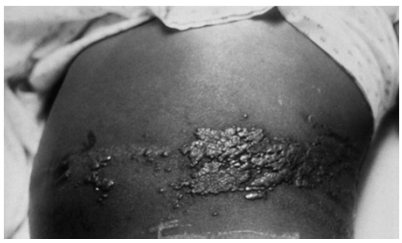
What Is This Infectious Disease?



Photograph courtesy of CDC Public Health Image Library

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Herpes Zoster

- Establishes latency in cells of dorsal root ganglia
- Reactivates and travels along neuronal cell axons
  - Often associated with advancing age or a weakened immune system
- Appears as localized rash in dermatomes
- Can cause the following complications:
  - Postherpetic neuralgia (PHN)
  - Scarring
  - Bacterial infection
  - Ocular abnormalities

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Zoster Vaccine

- Zostavax (Merck)
  - Live attenuated virus vaccine
  - Higher strength than varicella vaccine
- ACIP target group for vaccination
  - Adults ≥60 y/o
- FDA approved indication
  - Adults ≥50 y/o
  - Note: ACIP recommendations still are for 60 years and above and do not support 50-59 years for routine use.
- Dose and route
  - 0.65 mL (entire contents of vial) SC

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Zostavax (Zoster Vaccine Live)

- From the June 2011 package insert
  - In a randomized clinical study, a reduced immune response to Zostavax as measured by gpElisa was observed in individuals who received concurrent administration of Pneumovax 23 and Zostavax compared to individuals who received these vaccines 4 weeks. Consider administration of the two vaccines separated by at least 4 weeks.
- ACIP has not changed its recommendation regarding the simultaneous administration of zoster and pneumococcal vaccines

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Patient Case: Bob

- Bob is a 64 y/o man with an active case of herpes zoster. He has never had herpes zoster in the past and does not recall ever having chickenpox.
  - Should Bob receive the zoster vaccine?
    - The zoster vaccine is not indicated for treatment of an active case of zoster; however, it can help prevent future occurrences of the disease, so Bob should receive the vaccine
  - How long should Bob wait after his active herpes infection before receiving the zoster vaccine?
    - At this time, there is no specific recommendation for how long to wait after active herpes infection before administering the zoster vaccine
    - In general, a person should wait until the symptoms of herpes zoster have disappeared before getting vaccinated

Frequently Asked Question

- Can patients who receive the herpes zoster vaccine transmit the varicella zoster virus to susceptible persons?
  - Transmission of the varicella zoster virus from a vaccinated patient to a susceptible person has not yet been documented
  - If the patient develops a rash after vaccination—
    - It may be an active case of zoster because the vaccine is not 100% effective
    - The rash should be covered and susceptible persons should avoid contact with the lesions

Testing Your Knowledge

- How should varicella and zoster vaccines be stored?
  - Protect from light and store in freezer at –15°C (5°F) before use
  - Important note upon removal from freezer:
    - May be stored and/or transported at refrigerator temperature (2°C to 8°C, 36° F to 46°F) for up to 72 continuous hours prior to reconstitution
    - Vaccine stored at 2°C to 8°C (36°F to 46°F) that is not used within 72 hours of removal from –15°C (5°F) storage should be discarded

What Is This Infectious Disease?

Photograph courtesy of CDC Public Health Image Library

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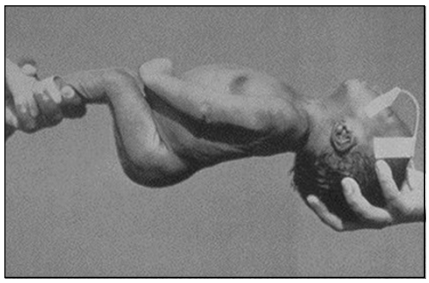
Neonatal Tetanus



Photograph courtesy of CDC Public Health Image Library

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Tetanus

- Caused by Clostridium tetani
- Spores ubiquitous; found in soil, dust, feces
- Toxin binds to CNS, prevents muscle relaxation
- Symptoms
  - Trismus (lockjaw)
  - Muscle rigidity and spasms
  - Death (10% case-fatality rate)

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Tetanus Transmission

- *How is tetanus transmitted?*
  - *Puncture wounds*
  - *Lacerations*
  - *Abrasions*
  - *Chronic wounds*
  - *Injection drug use*
  - *Amateur piercings and tattoos*
- *Where do these injuries occur?*
  - *Indoors or at home (45%)*
  - *Yard, garden, or farm (31%)*
  - *Other outdoor locations (23%)*

CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed. Washington DC: Public Health Foundation; 2011.

What Is This Infectious Disease?

Photograph courtesy of CDC Public Health Image Library

Diphtheria

Photograph courtesy of CDC Public Health Image Library

Diphtheria

- *Caused by Corynebacterium diphtheriae*
- *Complications due to absorbed toxin*
  - *Myocarditis, neuritis, death*
- *Common cause of death among children in early 1900s*
- *Epidemic in 1990s*
  - *In Russia, Ukraine, and nearby countries*
  - *157,000 cases and 5,000 deaths*

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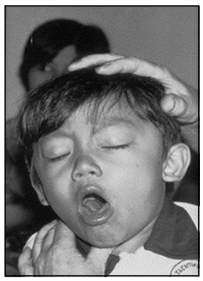
What Is This Infectious Disease?



Photograph courtesy of CDC Public Health Image Library

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Pertussis (Whooping Cough)

- *Caused by Bordetella pertussis*
  - *Very contagious*
- *Symptoms*
  - *Paroxysmal cough*
  - *Whooping caused by inspiration against a closed glottis*
- *Complications*
  - *Pneumonia, seizures, encephalopathy, hypoxia, hospitalizations, death*
- *Disease is more severe among children <5 y/o*

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Vaccines Available

- *Protect against tetanus, diphtheria, and pertussis*
  - *Diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP)*
  - *Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap)*
- *Protect against tetanus and diphtheria*
  - *Diphtheria and tetanus toxoids adsorbed (DT)*
  - *Tetanus and diphtheria toxoids adsorbed, adult (Td)*

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Differences Between DTaP and Tdap

- *Doses*
  - *Tdap has lower diphtheria and acellular pertussis dose to avoid local reactions in adults*
- *FDA-approved age indications*
  - *DTaP <7 y/o*
  - *Tdap*
    - *Boostrix (GSK) ≥10 y/o*
    - *Adacel (sanofi pasteur) 11–64 y/o*

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ACIP Recommendations for Tetanus, Diphtheria, and Pertussis Vaccines

Age of Patient	Recommendation
6 weeks to 6 years old	*Use DTaP to complete the primary series*
7 years to 10 years old who are not fully vaccinated against pertussis	*Give a single dose of Tdap*
11 to 64 years old	*If there is no record of a Tdap dose, give a single dose of Tdap followed by one dose of Td every 10 years*
≥65 years old	*If there is no record of a Tdap dose, give a single dose of Tdap followed by one dose of Td every 10 years*
Health Care Providers	*If there is no record of a Tdap dose, give a single dose of Tdap.*
Pregnant women (every pregnancy)	*Give a dose of Tdap after 20 weeks of gestation. (27-36 weeks optimal)*

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Applying Your Knowledge to Practice

- *A 32 y/o pregnant mother (33 weeks gestation) comes to the pharmacy to have a prescription filled for her 15-month-old son*
- *Her son's pediatrician told her that she should receive a vaccine to protect her from pertussis so she does not infect her son. She would like to receive the pertussis vaccine like her son did but she already had a Td last year*
- *She has two other children (10 y/o and 16 y/o) at home and wonders if they need the vaccine*
- *She states that her husband got a "tetanus shot" a few years ago and does not know what kind he got*
- *What do you tell this mother about the pertussis vaccine?*

Applying Your Knowledge to Practice

Patient vaccination history	What (if any) vaccine should the patient receive?
32 y/o Pregnant mother (33 weeks gestation) *Completed primary series with DTaP* *Last Td: 1 year ago*	Tdap
16 y/o son *Completed primary series with DTaP* *Last Td: 1 year ago during ER visit for wound*	Tdap
10 y/o daughter *Completed primary series with DTaP* *Last dose of DTaP was 5 years ago*	Tdap
35 y/o father *Completed primary series with DTaP* *Last "Tetanus shot": 2 years ago*	Tdap

Clinical Pearl

- *What is the recommended interval between a dose of Tdap and the last Td booster?*
  - *Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine*

Patient Case: James

- James is a 39 y/o man with no documentation of a primary series of tetanus and diphtheria toxoid–containing vaccines. You have made a considerable effort to locate his vaccination records but have been unable to do so.
- What would you recommend for James?
  - He should complete a three-dose primary series of tetanus and diphtheria toxoid-containing vaccines
    - 1st dose: Tdap
    - 2nd dose: Td administered 1 month after the first dose
    - 3rd dose: Td administered 6–12 months after the first dose

What Is This Infectious Disease?

Photograph courtesy of CDC Public Health Image Library

Hepatitis A

- Virus transmitted by the fecal-oral route
- Symptoms of hepatitis A
  - Jaundice (yellow skin and eyes)
  - Fever
  - Nausea
  - Vomiting
  - Dark urine
- Disease worse among adults than children

Target Groups for Hepatitis A Vaccination

- All infants ≥1 y/o
- People with chronic liver disease
- People receiving clotting factor concentrates
- Men who have sex with men
- Illicit drug users
- Travelers (except to Canada, W. Europe, Scandinavia, Japan, New Zealand, Australia)
- Close personal contacts of internationally adopted children arriving from hepatitis A endemic areas of the world
- People with occupational exposure to hepatitis A virus (working with HAV-infected primates or in HAV research lab)
- Any person for whom immunity against hepatitis A is desired

Hepatitis A Vaccination

- Routine vaccination
  - For all children 1–2 y/o
    - Catch-up by preschool if possible
- Catch-up vaccination
  - For adolescents and adults if risk factors are present or for any person for whom immunity against hepatitis A is desired

Hepatitis A Vaccines

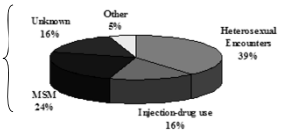
- Vaccines
  - Havrix (GSK) and Vaqta (Merck)
    - Brands interchangeable
- Give two-dose series at least 6 months apart
- Dose and route
  - Children 1–18 y/o 0.5 mL IM
  - Adults ≥19 y/o 1 mL IM

What Is This Infectious Disease?

Photograph courtesy of Patricia Walker, MD
Ramsey Clinic Associates, St. Paul, MN

Hepatitis B

Risk Factors



- Signs and symptoms
  - Jaundice, yellow skin and eyes, dark urine
- Complications
  - Acute: Fulminant hepatitis (1%–2%)
  - Chronic (10%): Cirrhosis, liver cancer, death

CDC. MMWR. 2006:55(RR-16):6-7.

Testing Your Knowledge

- *What are the target groups for hepatitis B vaccination?*
  - *All infants*
  - *All adolescents who have not been previously vaccinated*
  - *All high-risk adults [e.g., multiple sex partners, patients seeking treatment for STDs, patients with HIV infection, injection drug users, patients on dialysis, patients with chronic liver disease, health care providers, all diabetics 19-59 years (diabetics ≥60 years permissive)]*

Hepatitis B Vaccine

- Recommended schedule
  - Infants
    - Dose 1
      - Soon after birth
    - Dose 2
      - At age 1 or 2 months
    - Dose 3
      - No earlier than age 24 weeks
  - Adolescents and adults
    - 0, 1, 6 months

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Hepatitis B Vaccine

Age group	Recombivax HB		Engerix-B	
	Volume	# of doses	Volume	# of doses
0 to 19 y/o	0.5 mL	3	0.5 mL	3
11 to 15 y/o*	1 mL	2	-	-
≥20 y/o	1 mL	3	1 mL	3
Adults on dialysis	1 mL	3	2 mL	4

*The adult formulation of Recombivax is licensed for a 2-dose schedule for adolescents 11 to 15 y/o

What is the appropriate route of administration for hepatitis B vaccine?

It should be administered intramuscularly.

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Hepatitis B Vaccine

- Duration
  - After seroconversion, protection appears to persist indefinitely
    - Memory cells present, despite undetectable circulating antibody
    - No booster dose needed
  - ACIP discussing proof of immunity of Healthcare Personnel if titers not drawn previously.

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Human Papillomavirus (HPV)

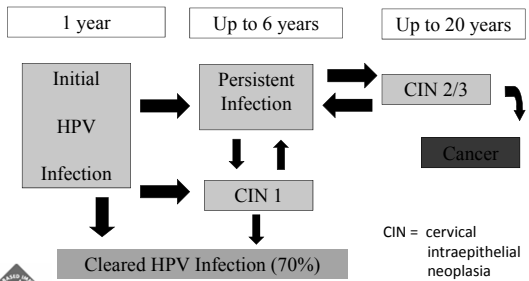
Human Papillomavirus Infection

- *Human papillomavirus (HPV)*
  - *Types (>100)*
    - *High-risk types 16*, 18*, 31, 33, 39, 45, 51, 52, 58*
      - *Cancers*
    - *Low-risk types 6*, 11*, 40, 42, 43, 44, 54*
      - *Low-grade Pap smear abnormalities, warts*
- *In United States, 20 million people are infected with HPV*
  - *Lifetime risk for sexually active adults is ≥ 50%*

**Most common types*

CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. 12th ed. Washington DC: Public Health Foundation; 2011.

Natural History of HPV



HPV Vaccines

- Gardasil (Merck)
  - Inactivated, quadravalent vaccine
  - Covers types 6, 11, 16, 18
  - Approved for prevention of cervical, vaginal, and vulvar, cancers (in female patients), and anal cancer and genital warts (in both female and male patients)
  - Prevention of certain precancerous or dysplastic lesions (CIN, VIN, VaIN, AIN)
- Cervarix (GSK)
  - Inactivated, bivalent vaccine
  - Covers types 16 and 18
  - Approved for prevention of cervical cancer in female patients

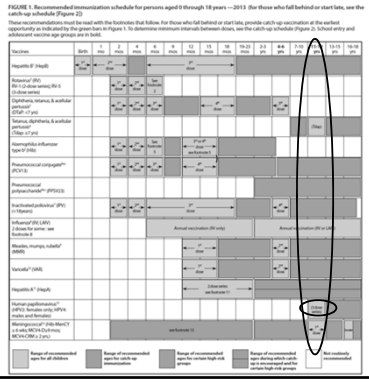
HPV Vaccines

- Dose and route
  - 0.5 mL IM
- Dosing intervals
  - Three doses total (0, 1–2, 6 months)
  - Second dose—1 to 2 months after first dose
  - Third dose—6 months after first dose

Applying Your Knowledge to Practice

- Mrs. Thomas is picking up an allergy medication for her 11 y/o daughter Allie. She asks you about an advertisement she saw on TV about a vaccine to protect teenage girls from cervical cancer. She is wondering if Allie needs to get this vaccine.
- Allie's immunization record reveals no vaccinations since she started kindergarten. She completed her primary series of DTaP, IPV, Hib, and two doses of MMR. She has not seen her pediatrician in 3 years.
- What do you tell Mrs. Thomas about the HPV vaccine?

Patient Case: Allie



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ACIP Recommendations for HPV Vaccine

- *Universal recommendation for girls and young women*
  - *Routine age: 11–12 years old (minimum age 9 years)*
  - *Catch-up age: 13–26 years old*
- *Universal recommendation for boys and young men (HPV 4 only)*
  - *Routine age: 11–12 years old (minimum age 9 years)*
  - *Catch-up age: 13–21 years old*
  - *Catch-up permissive: 22–26 years old*

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Patient Education

- *Mrs. Thomas wants to know why this vaccine is recommended at such a young age?*
  - *The vaccine is for the prevention of HPV, not the treatment of an active infection*
  - *Ideally, the vaccine should be given before the onset of sexual activity*
  - *Vaccination <u>before</u> exposure to any type of HPV will allow the individual to receive benefit against the HPV types in the vaccine*

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Syncope – HPV Vaccine

- 13% of all the reports to VAERS regarding Gardasil describe syncope
  - This percentage is similar to reports of syncope for other adolescent vaccines
- Individuals who faint after receiving Gardasil sometimes have tonic-clonic (jerking) movements and seizure-like activity
- Patients should remain seated or lying down and be closely observed by the provider for 15 minutes following vaccination

Meningococcal Disease

Meningococcal Disease

- Caused by Neisseria meningitidis
- Transmitted through respiratory droplets
- Symptoms
  - Meningitis
    - Pain, headache, neck stiffness
  - Bacteremia
    - Sepsis and rash
- Case fatality rate is high (10%–15%)

Meningococcal Vaccines

- Polysaccharide (MPSV4)
  - Tetravalent meningococcal polysaccharide vaccine
  - Types A C Y W-135
    - Menomune (sanofi pasteur)
- Conjugate (MCV4)
  - Meningococcal polysaccharide diphtheria toxoid conjugate vaccine
    - Menactra (sanofi pasteur)
  - Meningococcal oligosaccharide diphtheria CRM197 conjugate vaccine
    - Menveo (Novartis)
- Combination (HibMenCY)
  - Meningococcal Types CY and Haemophilus Influenza (Hib) tetanus toxoid conjugate vaccine
    - Menhibrix (GSK)

Testing Your Knowledge

- Which meningococcal vaccine is preferred?
  - MCV4 is preferred for adults aged ≤55 years
  - MPSV4 is preferred for adults aged ≥56 years
  - MPSV4 may be used if MCV4 is not available
- What are the FDA-approved age indications for the MCV4 vaccines?

Vaccine	Age Indications
Menactra	9 months–55 years
Menveo	2–55 years

Target Groups for Meningococcal Vaccination

- Adolescents
- Military basic training personnel
- College students living in dormitories
- Patients with asplenia (anatomic or functional)
- Travelers to "meningitis belt" of Africa or Saudi Arabia for Islamic Hajj pilgrimage
- Protection during outbreaks; work with health department

Infant Vaccination with Meningococcal Vaccine

- *Not recommended for routine use*
- *High Risk Infants –ACIP recommended*
  - *Complement deficiencies*
  - *Asplenia (including sickle cell anemia)*
  - *Travel to certain countries*
  - *Community outbreaks*
- *FDA Approved Infant Vaccines*
  - *Menactra (sanofi-pasteur) – high risk infants only*
    - *2 dose series 8 weeks apart (9-23 months of age)*
    - *Dose 0.5mL IM*
  - *Menhibrix (GSK)*
    - *4 dose series (2,4,6,12-15 months of age)*
    - *Dose: 0.5 mL IM*
    - *Used if Hib vaccine needed*
    - *Not for travel (only 2 serotypes)*
    - *Community outbreaks only if serotypes C and Y*
    - *If used, must complete all 4 doses.*

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Routine Vaccination with Meningococcal Vaccine

- *For all adolescents*
  - *Give one dose of MCV4 at age 11–12 years*
  - *Give one booster dose of MCV4 at age 16 years*
- *For persons with certain medical conditions (i.e., persistent complement component deficiency, anatomical or functional asplenia, HIV)*
  - *Give two doses of MCV4 at least 8 weeks apart*
- *For persons aged 20–55 years old*
  - *Routine vaccination is not recommended unless the patient is at high risk for infection*

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Catch-Up Vaccination with Meningococcal Vaccine

- *Catch-up vaccination*
  - *Give 1 dose of MCV4 for all previously unvaccinated adolescents aged 13–18 y/o*
  - *Give 1 booster dose of MCV4 at age 16–18 years for all adolescents who received the first dose of MCV4 at age 13–15 years*

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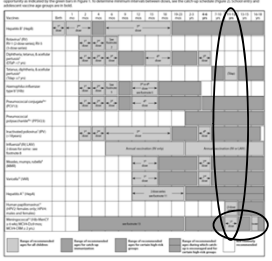
Revaccination with Meningococcal Vaccine

- *Children at continued risk for meningococcal disease who were previously vaccinated with MCV4 or MPSV4 should receive an additional dose of MCV4 after 3 years if the first dose was administered at age 2 through 6 years*
- *Persons who have completed the two-dose primary series and remain at continued risk for meningococcal disease should be revaccinated every 5 years after the last dose of the primary series*
- *Persons with persistent complement component deficiency or anatomic or functional asplenia should receive one dose of MCV4 every 5 years after completing the two-dose primary series with MCV4*

Do you remember Allie, the 11 y/o girl?

- *Would Allie be a candidate for meningococcal vaccine?*



Yes, Allie should receive 1 dose of MCV4 at age 11–12 years and then receive a booster dose at age 16 years.

What Is This Infectious Disease?

Photographs courtesy of CDC Public Health Image Library

Measles

- Respiratory transmission
  - Highly contagious
- Symptoms: fever ≥101°F, cough, coryza, conjunctivitis, Koplik spots, rash
- Complications
  - Diarrhea (8%)
  - Otitis media (7%)
  - Pneumonia (6%)
  - Encephalitis (0.1%)
  - Death (0.2%)

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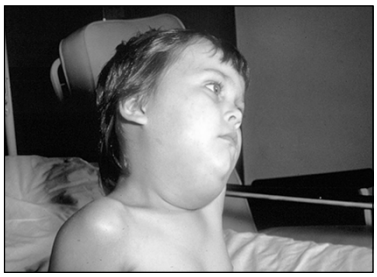
What Is This Infectious Disease?



Photograph courtesy of CDC Public Health Image Library

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Mumps

- Symptoms
  - Rash, headache, fever, malaise
  - Parotitis in 30%–40% of infections
- Complications
  - CNS involvement
  - Orchitis (up to 50% in postpubescent males)
  - Deafness
  - Death

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What Is This Infectious Disease?

Photograph courtesy of CDC Public Health Image Library

Rubella

- Generally mild disease
  - In adult women, infection is complicated by arthralgia or arthritis (50%–70%)
- Public health significance of rubella vaccination is to prevent congenital rubella syndrome (CRS)
  - Complications: Cataracts, heart defects, deafness, mental retardation, miscarriage
  - 1963–1964: worldwide pandemic; >20,000 babies born with CRS in the United States

Congenital Rubella Syndrome

Photograph courtesy of CDC Public Health Image Library

Cataracts Secondary to CRS

Photograph courtesy of CDC Public Health Image Library

Testing Your Knowledge

- What are the target groups for MMR vaccination?
  - All children
  - All susceptible people at high risk for disease
    - Health care personnel, college students, international travelers, and nonpregnant women of childbearing age without evidence of immunity to rubella, HIV patients if CD4 count adequate or if given before antiretroviral therapy.
  - Adults born in 1957 or later who have not been vaccinated with MMR

Applying Your Knowledge to Practice

Target group	How many doses of MMR should these patients receive?
All children	2 doses
All susceptible patients at high risk for disease (college students, international travelers)	2 doses
Health care personnel born before 1957	Consider 2 doses
Adults born in 1957 or later who have not been vaccinated with MMR	At least 1 dose; recommend a 2nd dose if a risk factor is present

What is the recommended dose and route of administration for MMR?

0.5 mL SC

What Is This Infectious Disease?

Photograph courtesy of Children's Immunization Project St. Paul, Minnesota

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Haemophilus influenzae Type b (Hib) Vaccine

- Before the vaccine was available—
  - Was the most common bacterial meningitis
  - Caused 1,000 deaths per year in children <5 y/o
  - Leading cause of acquired mental retardation
- After vaccine was available—
  - From 20,000 invasive infections among children <5 y/o in 1985 to 27 cases in 2008

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Target Groups for Hib Vaccine

- Infants and young children
- People without spleens (anatomic or functional)
- Sickle cell disease
- Hodgkin's disease
- Hematologic neoplasms
- Solid organ transplant
- Severe immunosuppression (non-HIV-related)
- People with HIV infection

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Haemophilus influenzae Type b Vaccines

- *Three conjugated vaccines*
  - *ActHIB (sanofi pasteur)*
  - *PedvaxHIB (Merck)*
  - *Hiberix (GSK)*
    - *Only approved for the booster dose*
- *One combination vaccine (with Meningococcal vaccine)*
  - *Menhibrix (GSK)*
- *Dose and route: 0.5 mL IM*
- *Primary series: Give one dose at 2 months of age, and follow with one or two additional doses depending on vaccine brand*
- *Booster dose: Give one dose at 12–15 months*

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April 2013

What Is This Infectious Disease?

Photograph courtesy of CDC Public Health Image Library

- *Poliomyelitis*
  - *Can destroy the anterior horn cells of the spinal cord, leading to flaccid paralysis of muscles, leaving sensory function intact*

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Poliomyelitis Vaccine

- *IPOL (sanofi pasteur)*
- *Target groups for vaccination*
  - *All infants (routine)*
    - *2, 4, 6–18 months, 4–6 years*
  - *International adult travelers to polio-endemic areas*
- *Dose and route: 0.5 mL IM (or SC)*
- *Important to keep vaccinating until WHO certifies global eradication of this disease*

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April 2013

Rotavirus

Rotavirus Gastroenteritis

- Symptoms: Diarrhea (may lead to dehydration), fever, vomiting
- Infects >95% of all children by 5 y/o
- Estimated rates in children ≤5 y/o in the United States annually before vaccine
  - 2.7 million cases/year
  - 205,000–272,000 emergency department visits
  - 55,000–70,000 hospitalizations

MMWR Recomm Rep. 2009;58(RR-2):1–28.

Rotavirus Vaccines

- Previous vaccine
  - RotaShield (Wyeth)
  - Withdrawn from market in 1999
    - Increased incidence of intussusception
- New vaccines
  - Live attenuated vaccines
    - RotaTeq (Merck)
      - Oral suspension in ready-to-use dosing tubes
    - Rotarix (GSK)
      - Oral vaccine requires reconstitution before administration

Rotavirus Vaccines

- *Recommended schedule*
  - *RotaTeq: three-dose series (2, 4, 6 months of age)*
  - *Rotarix: two-dose series (2, 4 months of age)*
- *Ages for administration*
  - *Minimum age for first dose: 6 weeks*
  - *Maximum age for first dose: 14 weeks 6 days*
  - *Maximum age for final dose: 8 months 0 days*

Testing Your Knowledge

- *Who should receive the rotavirus vaccine?*
  - *Any child at the appropriate age without a valid contraindication or precaution to receiving the vaccine*
- *Who should not receive the rotavirus vaccine?*
  - *Any child with a valid contraindication or precaution to receiving the vaccine*
    - *Contraindications*
      - *Serious reaction to vaccine component or previous dose*
      - *Infants diagnosed with severe combined immunodeficiency*
      - *History of intussusception or uncorrected congenital malformation that would predispose to intussusception*
      - *History of anaphylaxis to latex (for Rotarix only)*
    - *Precautions*
      - *Acute gastroenteritis*
      - *Moderate to severe illness*
      - *Preexisting GI disease*
      - *Immunosuppression*

Vaccine Combinations

Some combinations are indicated only for certain ages or certain doses in a series; consult package inserts.

- *Comvax (Merck) - Hep B + Hib*
- *DTaP*
  - *Infanrix (GSK)*
  - *Daptacel (sanofi pasteur)*
- *Tdap*
  - *Adacel (sanofi pasteur)*
  - *Boostrix (GSK)*
- *Td (various)*
- *Kindrix (GSK) - Tdap + IPV*
- *Pentacel (sanofi pasteur) - DTaP + Hib + IPV*
- *Pediarix (GSK) - DTaP + HepB + IPV*
- *Twinrix (GSK) - Hep A + Hep B*
- *ProQuad (Merck) - MMR + Varicella*
- *MenHibrix (GSK) – Men CY + Hib*

International Travel Medicine

- Recommendations for travel are complex
  - More than just vaccines
  - Variety of diseases to consider
    - Typhoid
    - Yellow fever
    - Japanese encephalitis
    - Malaria
    - Parasites
    - Many more
- Need advanced training in travel medicine

Bioterrorism Threats

- Anthrax
  - BioThrax (Emergent BioSolutions)
- Smallpox
  - ACAM2000 (Acambis)
- Other threats
  - Botulism
  - Plague
  - Tularemia
  - Viral hemorrhagic fevers
  - Ricin
- Specialized training is necessary

What's New in the Pipeline

- Helicobacter pylori
- HIV
- TB vaccine
- Herpes simplex vaccine
- RSV vaccine
- Epstein-Barr virus
- Salmonella
- Cytomegalovirus
- Group A and B streptococci
- Hepatitis C
- Malaria
- Staphylococci
- Adenovirus
- Campylobacter jejuni
- Encephalitis (multiple)
- Parainfluenza
- Escherichia coli
- Shigella

Questions?

Identifying Vaccination Needs

Applying Your Knowledge to Practice

- *Steve is a 43 y/o pharmacist. He will be offering a pharmacy-based immunization program for the first time this year. It is early October and he is preparing for the first influenza clinic at his pharmacy. Steve is healthy and takes no chronic medications. He does not smoke.*
- *Steve's immunization record reveals the following:*
  - *Inactivated influenza—yearly*
  - *Tetanus-diphtheria—2 years ago*
  - *Hepatitis A two-dose series—6 years ago*
  - *MMR two-dose series—10 years ago*
  - *Physician-documented case of chickenpox*
- *What vaccinations should be recommended for Steve?*

Patient Case: Steve (continued)

Figure 2. Vaccines that might be indicated for adults based on medical and other indications[1]

VACCINE ▼ INDICATION ►	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV])[4,6,7,14]	HIV infection[4,7,13,14] CD4+ T lymphocyte count < 200 cells/μL	HIV infection CD4+ T lymphocyte count ≥ 200 cells/μL	Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia[13] (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Diabetes, kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Influenza [2]	1 dose TIV annually				1 dose TIV or LAIV annually	1 dose TIV annually				1 dose TIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) [3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs									
Varicella [4,*]	Contraindicated			2 doses						
Human papillomavirus (HPV) Female [5,*]		3 doses through age 26 yrs				3 doses through age 26 yrs				
Human papillomavirus (HPV) Male [5,*]		3 doses through age 26 yrs				3 doses through age 21 yrs				
Zoster [6]	Contraindicated				1 dose					
Measles, mumps, rubella (MMR) [7,*]	Contraindicated			1 or 2 doses						
Pneumococcal (polysaccharide) [8,9]	1 or 2 doses									
Meningococcal [10,*]	1 or more doses									
Hepatitis A [11,*]	2 doses									
Hepatitis B [12,*]	3 doses									

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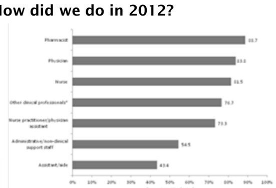
Vaccination of Health Care Personnel Policy of APhA

2011 Policy (Adopted During APhA2011 House of Delegates)

1) APhA supports an annual influenza vaccination as a condition of employment, training, or volunteering, within an organization that provides pharmacy services or operates a pharmacy or pharmacy department (unless a valid medical or religious reason precludes vaccination).

How did we do in 2012?



http://www.cdc.gov/flu/fluvaxview/hcp-ips-Nov2012.htm

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Patient Case: Steve (continued)

- *Can Steve receive all the recommended vaccinations at the same visit?*
  - *Yes, there are no contraindications to simultaneous administration of any routinely administered vaccines*
- *How would you administer the recommended vaccines?*
  - *Use separate syringes, needles, and injection sites*
    - *It is recommended to use both arms if two or more injections will be administered*
    - *If administered in same arm, separate by at least 1 inch*

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Summary: Intervals Between Vaccines

If you do not administer vaccines simultaneously, what is the minimal interval that must be observed between vaccines?

Vaccines	Minimum Interval
Two inactivated vaccines	*No minimum*
Inactivated and live vaccines	*No minimum*
Two live vaccines, if not simultaneous	*28-day minimum interval*
Inactivated vaccines and antibodies	*No minimum*
Live vaccines followed by blood products	*2 weeks*
Blood product given before live vaccine	*Minimal interval varies (look up)*
Live vaccine followed by PPD skin test	*28-day minimum interval*
PPD skin test followed by live vaccine	*Administer vaccine after PPD skin test has been read*

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Patient Case: Steve Follow-Up

- *Steve received all of his recommended vaccinations. However, his immunization program was so successful and he was so busy that he did not complete the hepatitis B vaccine series as scheduled.*
- *What would you recommend to Steve at this time?*

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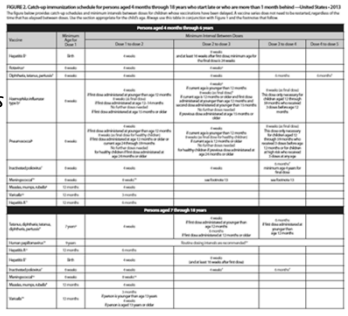
Catch-Up Schedule

- *Use minimum acceptable interval between doses when trying to "catch up"*
- *Do not count doses inside the minimum*



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Grace Period

- *Minimal Interval on Catch-up Schedule*
  - *Most is 28 days*
- *Administration slightly earlier probably not going to interfere with antibody production*
  - *ACIP Grace Period ≤ 4 days*
  - *Applies to same antigen live vaccines*
  - *Does not apply to different live vaccines*
  - *Oral, live vaccines do not have this restriction and do not have interval rules (typhoid, rotavirus)*
- *Different live vaccines may have interference if interval less than 28 days*
  - *Grace period cannot be applied to sequential dosing of MMRV or MMR and Varicella*

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Applying Your Knowledge to Practice

- *What happens if the interval between vaccine doses in a series is decreased?*
  - *Decreasing the interval between doses may interfere with antibody response and protection*
- *What happens if the interval between vaccine doses in a series is increased?*
  - *Does not reduce vaccine effectiveness but it does delay protection for the patient*

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Establishing a Pharmacy-Based Immunization Program

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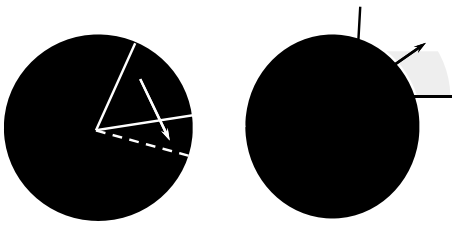
Hoping Your Practice Will Grow?

- Two kinds of market share*



*Not to scale

J Am Pharm Assoc. 2001;41:46-52; Medical Care. 2001;39:340-8; J Clin Epidemiol. 2001;55:279-84.

Steps to Becoming a Vaccine Provider

- Receive specialized training and stay up to date
- Identify what is allowed by state laws and regulations
- Identify unmet needs in your community
- Develop program materials
- Modify practice to incorporate program
- Identify sources for vaccine compensation

Getting Started

- Create a list of things to do and supplies to get
- Taking the first step is hard
  - Who will be your role model?
  - Who will you call for support or advice?
  - What is your timeline?
  - What is a reasonable expectation for implementing your program?

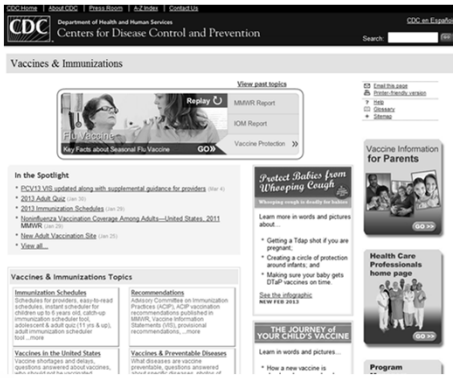
Sample Planning Timeline

Task	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
Determine local needs	x											
Talk to physicians		x										
Research reimbursement options		x										
Attend training				x								
Check legal/liability obligations			x									
Design facility			x									
Assemble supplies				x								
Assemble documents				x								
Order software				x								
Order vaccines					x							
Consider disposal options			x									
Develop marketing plan			x									
Train staff					x	x			x			x
Immunize and document						x	x	x	x	x	x	x
Report immunizations						x	x	x	x	x	x	x
Review program												x

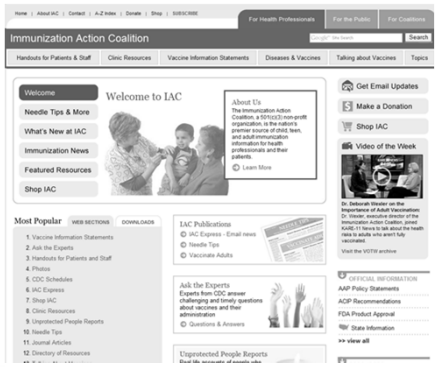
Immunization Resources: Staying Up to Date

- *Read the literature; keep current references*
- *APhA Pharmacist Immunization Center*
  - *www.pharmacist.com/immunization-center*
- *APhA Immunization e-Community*
- *Electronic mailing lists*
  - *IAC Express: express@immunize.org*
  - *Immunizing Pharmacists News (APhA): sign up by filling out the form at: www.pharmacist.com/immunizing-pharmacist-news-mailing-list*
  - *MMWR: subscribe at www.cdc.gov/mmwr*
- *Attend refresher/advanced practice courses*
  - *APhA Annual Meeting*
- *Collaborate (e.g., associations, coalitions)*
  - *New APhA Immunization SIG*
- *Pharmacist.com CPE Center*

What resources did you find on the APhA website that would be valuable to your practice?

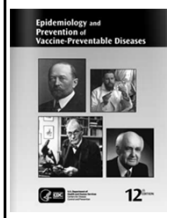


What resources did you find on the CDC website that would be valuable to your practice?



What resources did you find on the IAC website that would be valuable to your practice?

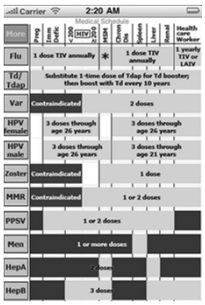
Epidemiology and Prevention of Vaccine-Preventable Diseases



- *Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 12th ed. Washington, DC: Public Health Foundation; 2011.*
- *Order online from: http://bookstore.phf.org*
- *PDF files available online:*
  - *www.cdc.gov/vaccines/pubs/pinkbook/index.html*

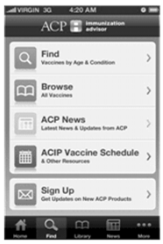
Application for iPhone or Android

- *Shots by STFM*
  - *Provides up-to-date immunization schedules*
  - *Updated yearly*
  - *Produced by the Society of Teachers of Family Medicine*
  - *Available at:*
    - *www.immunizationed.org*
    - *Android market*
    - *Apple app store*



Another App

- *American College of Physicians*
  - *iPhone or iPad*
  - *4 sections*
    - *Practice Improvements*
    - *Practical Advise*
    - *Vaccines and indications*
    - *Special Programs*
  - *Available at:*
    - *http://immunization.acponline.org/app/*
    - *Apple Store*



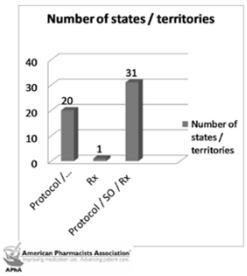
Legal and Regulatory Issues

Prescribing Authority

- *State law governs health care practice*
- *State-specific prescribing regulation*
  - *Written or verbal prescriptions*
  - *Standing orders*
  - *Protocols, collaborative agreements*
- *Applies to both vaccines and epinephrine*

Pharmacist-Administered Vaccines Protocols vs. Rx

Based upon APhA / NASPA Survey of State IZ Laws/ Rules (updated June 2012)



Protocol or Standing Order	AK, CA, CO, CT, FL, ID, KS, KY, MN, MS, MT, ND, NH, NM, NV, NY, OK, OR, UT, WI
Rx	AL
Protocol , Standing Order or Rx	AR, AZ, DC, DE, GA,HI, IL, IN, IA, LA, ME, MD, MA, MI, MO, NE, NJ, NC, OH, PA, PR, RI, SC, SD, TN, TX, VT, VA, WA, WV, WY

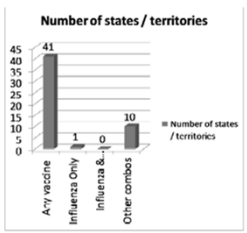
Changes occur frequently.

Authority to Administer

- *"Practice of pharmacy" shall mean a health care service that includes, but is not limited to, the compounding, dispensing, and labeling of drugs or devices; interpreting and evaluating prescriptions; administering and distributing drugs and devices.*

Pharmacist-Administered Vaccines by Types Authorized to Administer

Based upon APhA / NASPA Survey of State IZ Laws/ Rules (updated June 2012)



Any vaccine	AL*, AK*, AZ*, AR*, CA, CO, CT, DC*, DE*, GA*, HI*, ID,IL, IN*, IA*, KS, KY, LA*, MA, ME, MI*, MN, MS, MT, NE, NV ,NJ*, NM, NC, ND, OK, OR, PA, RI, SC*, TN, TX, VT, VA*, WA, WI
Influenza Only	PR
Influenza and Pneumo	
Other combos	OH, FL, MD, MO, NH, NY, SD, UT, WV, WY

American Pharmacists Association APhA

* Via Rx for some; ** broad list of vaccines

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Changes occur frequently.

Pharmacy Technicians

- *Warning: No states permit pharmacy technicians to administer medications (including immunizations)*
- *Pharmacists who allow technicians to administer are jeopardizing their programs and practices*

Think it Through…

What tasks can be delegated to pharmacy technicians to free up the pharmacist to administer vaccines?

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Student Pharmacists

- *Read state law and regulations to determine what degree of student involvement is permitted*
  - *Students must work under the direct supervision of a pharmacist*
    - *The supervising pharmacist must be legally allowed to provide immunizations*
  - *Students must be trained and educated*

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Identify Needs in Community

- *Identify unmet needs in community*
  - *Work with local/state health department*
  - *Become a part of local/state immunization coalition*
- *Gain acceptance by other providers*
- *Collaborate with health departments, local physicians, medical societies, other boards*
- *Educate health care providers and the public about pharmacist involvement in immunizations*

Develop Partnerships in Community

- *Pharmacists should develop relationships with the local health department to maximize vaccination efforts*
- *Association of State and Territorial Health Officials released a document titled "Operational Framework for Partnering with Pharmacies for Administration of 2009 H1N1 Vaccine" (www.astho.org)*
  - *Provided guidance to state health departments on how to work with pharmacists during the 2009–2010 influenza pandemic and beyond*
    - *One key message: multiple partners must collaborate with one another to coordinate efforts to fully vaccinate the U.S. population*

Physician Authorization of Standing Orders/Protocols

- *Ask a physician who already knows you*
- *Make an appointment*
- *Take all the training materials with you to show commitment to best vaccine practices*
- *Highlight local needs and ask for cooperation in preventing needless deaths*
  - *"Let's work together on this problem for the good of our community."*

Information to Include in a Standing Order/Protocol

- Physician authorization
  - Pharmacist's authority to screen and vaccinate
- Qualifications of person(s) administering vaccines
- Vaccine(s) covered in the standing order/protocol
- Policies
  - How to screen patients for indications and contraindications
  - What information must be provided to patient (e.g., VIS)
  - How to administer vaccine (e.g., dose, route, anatomic location)
  - Documentation requirements
  - Communication to physician and reporting requirements
- Emergency precautions
  - Specific protocol should be included

Goad JA. Pharm Today. 2007;13(10):77–91.

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Professional Liability

- Common themes in malpractice litigation
  - Negligence and failure to warn
- Receive specialized training and stay up to date
- Act prudently (within scope of practice)
- Mimic local standards and safeguards
- Inform patients of risks and benefits of vaccination

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Professional Liability

- Physician's liability does not encompass the pharmacist's scope of practice
- Physician is not liable for pharmacist's error in dispensing (analogous to immunizing)
- Verify that liability insurance covers all your professional services
- Some vaccines covered for both children and adults under federal no-fault VICP
  - Protected only if documentation and event reporting occurs

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National Childhood Vaccine Injury Compensation Act

- VICP (Vaccine Injury Compensation Program) Act established no-fault insurance against certain adverse reactions
  - VIT: vaccine injury table lists specific injuries
- Removed liability from manufacturers and providers (except in negligence cases)
  - Petitioners waive right to claim punitive damages
- Current VIS must be given to all patients regardless of age before vaccination
- Must report adverse event to VAERS

VIT—Condensed (VAERS Reports Required)

- Anaphylaxis
- Encephalopathy or encephalitis
- Brachial neuritis after tetanus toxoid (any form)
- Chronic arthritis after rubella vaccine (any form)
- Thrombocytopenic purpura after measles vaccine
- Vaccine-strain measles infection in immunodeficient person after any form of measles vaccine
- Paralytic polio or poliovirus infection after OPV
- Intussusception after rotavirus vaccine
- Any acute sequelae of these events (including death)

www.vaers.hhs.gov/reportable.htm

Vaccine Adverse Event Reporting System (VAERS)

www.vaers.hhs.gov

Vaccine program analogous to MedWatch program

Occupational Safety and Health Administration (OSHA)

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OSHA Bloodborne Pathogens Standard

- *Requires training with annual updates**
- *Requires use of universal precautions*
- *Requires an exposure control plan (ECP)*
- *Requires employer to provide hepatitis B vaccine to employees with potential risk*
- *Mandates use of safer devices (safety needles)*
- *Requires documentation of safety device evaluation*
- *Requires a sharps injury log*
- *Requires employees to sanitize hands after removal of gloves*

**OSHA requires specific training that is not included in this course*

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OSHA Regulations and Hepatitis B

- *Immunizing pharmacists need hepatitis B vaccine (must start series before giving immunizations)*
- *Vaccine must be offered without charge to any employee with potential contact with blood products*
- *Declination of vaccine must be in writing, using specified wording*
  - *If individual employee changes mind, must provide hepatitis B vaccine*

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Use of Safety Devices

- OSHA mandates the use of safety devices to reduce risk of exposure to bloodborne pathogens
- Requires employer to evaluate available safety devices, choose device, and document evaluation by front line employees
  - Nonmanagerial employees must be included in the evaluation of devices
- OSHA does not approve, endorse, register, or certify any medical devices

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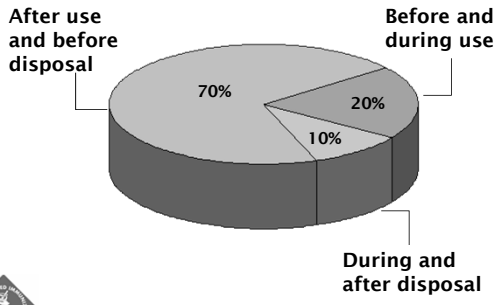
When Do Needlesticks Happen?



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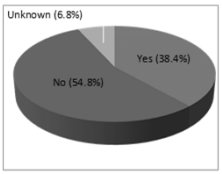
Can Needlesticks Happen With Safety Devices?

- If injury was caused by a needle, was it equipped with a safety device?



Needlesticks can still happen even when using safety devices.

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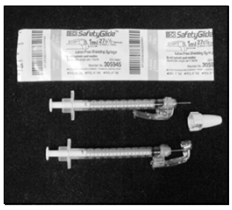
www.healthsystem.virginia.edu/internet/epinet/EPINet-2004-rates.pdf

Examples of Safety Devices

Needle Shields

More devices are listed at: www.healthsystem.virginia.edu/internet/epinet

Examples of Safety Devices



Retractable Needle *Needle Guard*

More devices are listed at: www.healthsystem.virginia.edu/internet/epinet

OSHA Citations

- *Failure to have an exposure control plan*
- *Failure to review and implement commercially available "safer medical devices"*
- *Failure to include procedures for documenting exposure incidents*
- *Failure to review and update plan annually*
- *Failure to follow universal precautions*
- *Failure to comply with most current CDC recommendations for post-exposure evaluation and follow-up*
- *Recapping needles before discarding*

More OSHA Information

Additional information can be obtained at:
www.cdc.gov/niosh
www.osha.gov

- *NOTE: The information in this course does not meet the requirements for annual OSHA training.*

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Modifying Your Practice

- *Facility layout*
  - *Patient privacy*
  - *Appropriate refrigerator and/or freezer*
  - *Place for dose preparation, supplies*
  - *Seating/waiting area*
- *Services: Biohazardous waste disposal*
- *Program costs and setup (i.e., exposure control plan, staff training, supplies, and marketing materials)*

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Work-Flow Options

- *Who will provide the vaccines?*
- *How will you incorporate immunizations into your practice?*

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Time-Motion Analysis

"After a little practice, immunizing one patient takes about the same amount of time as filling one prescription."

John Beckner and Dennis Stanley, Ukrops, verbal communication; 1999.

Hint: Let professionals do professional tasks, technicians do technical tasks.

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Vaccine Storage and Management

- *Never take chances with your vaccines*
  - *Institute storage rules before you purchase your vaccine*
- *Protect your patients*
- *Protect your expensive inventory*

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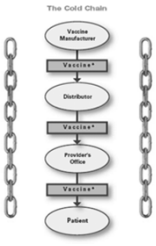
The "Cold Chain"

- *Vaccine stability is only as good as the weakest link in the cold chain*
  - *Have delivery only when trained personnel can accept; train everybody*
  - *Unpack vaccines immediately*
  - *Check temperature indicators and ice packs in shipping case*



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New Vaccine Management Guidelines – October 2012

- Guidelines available at:
  http://www.cdc.gov/vaccines/recs/storage/interim.htm
- Use a biosafe glycol-encased probe rather than measurement of ambient air temperatures
- Use a digital data logger for continuous 24 hour temperature monitoring
- Use stand-alone refrigerator and stand-alone freezer
  - Do not use combination refrigerator/freezer
  - Discontinue dorm-style or bar-style
  - Post warning signs at outlets and circuit breaker not to interrupt refrigerator power
- Weekly review of expiration dates and rotation of stock

Breaks in the Cold Chain

- Document breaks in the cold chain
  - Monitor and document if temperature has strayed outside recommended range
- If you suspect the cold chain is broken—
  - Separate suspect vaccines from other stock
  - Mark "Do Not Use"
  - Store in the refrigerator or freezer
  - Contact health department or manufacturer for guidance

What Would You Do?

- You are asked to prepare a dose of zoster vaccine for a patient. The patient wants to transport the vaccine to the physician's office for administration. What would you do in this situation?
  - You are responsible for maintaining the cold chain until the vaccine is administered to the patient
  - Avoid premixing expensive or temperature-sensitive vaccines (e.g., zoster)
  - Do not let the patient transport

Vaccine Compensation

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Vaccine Compensation

- *Out-of-pocket (i.e., self-pay)*
- *Patient reimbursement through employer plans*
  - *Applied to deductibles, health savings accounts, or flexible spending accounts*
- *Private employers (to reduce absenteeism)*
- *Medicare (Part B, Part D)*
- *Medicaid*
- *Third-party insurance payers*
- *Affordable Care Act (ACA)*

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Reimbursement Medicare Part B

- *Request a National Provider Identification (NPI) Number from CMS*
- *Request to become a mass immunization provider through the local carrier using the appropriate Form CMS-855*
  - *Allow 4–8 weeks for provider number*

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Billing Medicare Part B

- Vaccines covered under Medicare Part B
  - Influenza
  - Pneumococcal
  - Hepatitis B (for select group of patients)
- Submit claims electronically or on Form CMS-1500
  - Use roster billing when submitting Form CMS-1500
- Billing resources are available at: www.cms.hhs.gov/AdultImmunizations/

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Medicare Reimbursement

- Formula for Medicare reimbursement for vaccines
  - Vaccine cost + administration fee
    - Nationally established payment for the cost of the vaccine
      - Vaccine cost is calculated at 95% of AWP
  - Compensation for vaccine administration fee can vary from one geographic area to another
- Patient pays no deductible, no co-pay on Medicare Part B vaccines
- Pharmacists must accept Medicare rates as payment in full

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Medicare Part D

- Prescription drug coverage
  - All vaccines not covered under Part B will be covered under Part D
- Coverage may vary among plans
  - Patient will pay deductibles and co-pays
- Pharmacy should bill the beneficiary's Part D plan for the vaccine product and administration
  - Pharmacy will receive the contracted rate for both elements

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Billing Third-Party Payers

- Pharmacist should bill the payer for the vaccine product + administration
- Pharmacists should use specific codes when submitting claim
  - Reason for Service Code (NCPDP Field 439-E4)
    - PH = Preventive Health Care
  - Professional Service Code (NCPDP Field 440-E5)
    - MA = Medication Administration
  - Result of Service Code (NCPDP Field 441-E6)
    - 3N = Medication Administration
- Even if payer does not cover administration, pharmacists should have a mechanism in place for receiving compensation from the patient for administration

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Compensation Pearls

- Tell patients what the charge will be for the vaccine and your service before you prepare the dose
  - You cannot charge Medicare or other third-party payers more than your usual and customary fee
- Give all cash-paying patients a receipt so they can seek reimbursement from insurance

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Vaccines for Children (VFC) Program

- Federally funded, state-operated program
- Patient eligibility
  - Children <18 y/o who meet any of the following criteria:
    - Uninsured or underinsured
    - Medicaid eligible
    - American Indian or Alaskan Native
- Provider may charge modest administration fee; however, no child may be turned away for inability to pay fee

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Marketing Your Immunization Program

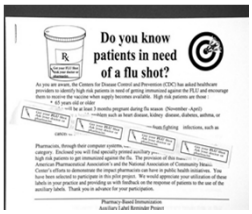
Marketing Your Program

- *To whom will you market your immunization program?*
  - *Patients*
  - *Health care providers*
  - *Community*
  - *Employees*
  - *Employer groups*
  - *Other pharmacists*

Marketing Tools

- *How will you market your program?*
  - *Word of mouth*
  - *Media: Print, radio, television, newspapers, website*
  - *Storefront displays*
  - *Flyers, posters, bag stuffers*
  - *Circulars or weekly advertisements*
  - *Overhead announcements*
  - *Business cards*
  - *Direct mail: Personalized (HIPAA compliant)*
  - *Buttons, stickers*
  - *Auxiliary labels*

Prescription Vial Auxiliary Labels

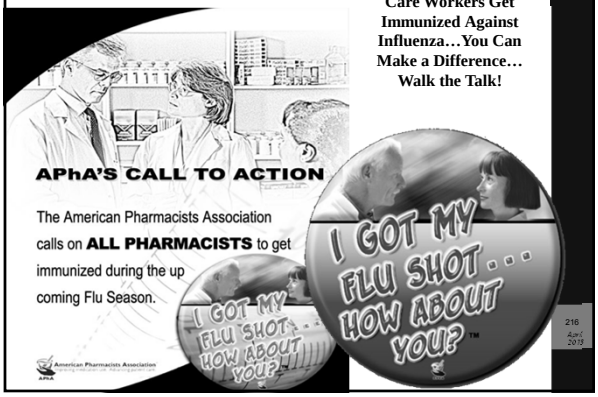


These labels can be ordered from APhA at http://fs16.formsite.com/APhA/IZButtonsandLabels/index.html.

The Personal Touch in Marketing Vaccinations

- *Personal contact is the most effective way to convince people of the value of your service*
- *Applies at all levels: Patients, health departments, physicians, other professionals, nursing homes, discharge planners*
- *Identify the other person's needs before you speak*
- *Follow up with a thank-you letter or note to reinforce your message*
- *Invite key people to visit your pharmacy*

Only 53% of Health Care Workers Get Immunized Against Influenza…You Can Make a Difference… Walk the Talk!



Providing Vaccinations to Patients

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Applying Your Knowledge to Practice

- *Pat is a 67 y/o woman who presents to your pharmacy during October for medication refills for heart failure. Pat will be traveling to Arizona to see a new grandchild. She asks about getting an influenza vaccination and the "pneumonia" vaccine.*
- *What is the first question you want to ask Pat about immunizations?*

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Patient Case: Pat (continued)

- *Pat's immunization card reveals the following:*
  - *Inactivated influenza—yearly*
  - *Pneumococcal vaccine—6 years ago*
  - *Tetanus-diphtheria—1 year ago*
  - *Hepatitis A series—5 years ago*
- *What vaccinations are recommended for this patient?*

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Patient Case: Pat (continued)

Figure 2. Vaccines that might be indicated for adults based on medical and other indications

VACCINE ▼ INDICATION ►	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV])[4,6,7,14]	HIV infection[4,7,13,14] CD4+ T lymphocyte count < 200 cells/µL	HIV infection CD4+ T lymphocyte count ≥ 200 cells/µL	Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia[13] (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Diabetes, kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Influenza[2]	1 dose TIV annually				1 dose TIV or LAIV annually	1 dose TIV annually				1 dose TIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap)[3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs									
Varicella[4,*]	Contraindicated			2 doses						
Human papillomavirus (HPV) Female[5,*]		3 doses through age 26 yrs				3 doses through age 26 yrs				
Human papillomavirus (HPV) Male[5,*]		3 doses through age 26 yrs				3 doses through age 21 yrs				
Zoster[6]	Contraindicated				1 dose					
Measles, mumps, rubella (MMR)[7,*]	Contraindicated			1 or 2 doses						
Pneumococcal (polysaccharide)[8,9]		1 or 2 doses								
Meningococcal[10,*]	1 or more doses									
Hepatitis A[11,*]	2 doses									
Hepatitis B[12,*]	3 doses									

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Screening Patients to Identify Contraindications and Precautions

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Key Interview Questions

For all vaccines:

- *"Are you sick today?"*
- *"Do you have allergies to medications, food, a vaccine component or latex?"*
- *"Have you ever had a serious reaction after receiving a vaccination?"*
- *"Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder?"*

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Key Interview Questions (continued)

Caution with live vaccines:

- *"Do you have cancer, leukemia, AIDS, or any other immune system problem?"*
- *"In the past three months, have you taken medications that weaken the immune system, such as cortisone, prednisone, other steroids, or anticancer drugs, or have you had radiation treatments?"*
- *"During the past year, have you been given a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?"*

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Key Interview Questions (continued)

Caution with live vaccines:

- *"Have you received any vaccinations in the past 4 weeks?"*
- *For women: "Are you pregnant or is there a chance you could become pregnant during the next month?"*

Caution with pertussis-containing vaccines:

- *"Have you had a seizure, brain, or other nervous system problem?"*

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Patient Case: Pat (continued)

- *Pat is a candidate for TIV, Tdap, PPSV, and zoster vaccine.*
- *What specific screening questions would you ask Pat before administering the vaccines?*
- *Why do you need to ask these screening questions?*

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General Rule—Contraindications

- *A condition that greatly increases the risk of an adverse reaction*
- *Vaccine likely to injure patient*
- *Do not vaccinate*
- *Universal contraindication for all vaccines*
  - *Severe allergy (immediate and life-threatening anaphylaxis) to a vaccine component following a previous dose*

False Contraindications

- *Minor illness (mild fever, upper respiratory infection, otitis media, mild diarrhea)*
  - *Vaccine should not be given if you discern that the patient is ill enough to refer to physician or hospital*
- *Allergies to products not in the vaccine (e.g., penicillin, bird feathers)*
- *Allergies that are not immediate and life-threatening (e.g., other than anaphylaxis or laryngeal edema)*

False Contraindications (continued)

- *Pregnancy in the household (even varicella)*
- *Breastfeeding (even rubella)*
- *Premature birth (do not adjust for gestation)*

General Rule—Precautions

- A condition that may increase the risk of an adverse reaction OR a condition that may compromise vaccine efficacy
- Vaccine may cause injury OR may decrease effect
- Precautions (temporary contraindications)
  - Substantial illness (resolve acute need, then vaccinate)
  - Pregnancy
  - For live vaccines, receipt of blood product or immunosuppression

Vaccines and Pregnancy

- Encourage women to be fully vaccinated prior to pregnancy
- Inactivated seasonal influenza vaccine is recommended for any patient who will be pregnant during influenza season
- Tdap is recommended for every pregnancy after 20 weeks gestation. (27 to 32 weeks ideal)
- Avoid giving other vaccines to women who are or might become pregnant (especially live vaccines); risks are theoretical
  - Pregnant providers may administer live vaccines
- If vaccinations are deemed necessary during pregnancy, discuss with the patient's physician or refer the patient to the physician for vaccine decisions
- After pregnancy, administer any deferred vaccines

Immunosuppression

- Congenital immunodeficiency
- Leukemia, lymphoma, generalized malignancy
- Hematopoetic cell transplant patients
- HIV infection
  - Depending upon degree of immunosuppression
- Radiation therapy or chemotherapy
- Prednisone
  - Dose equivalent to ≥2 mg/kg of body weight or a total of 20 mg/day for persons who weigh >10 kg, when administered for >2 weeks
- Monoclonal antibodies, TNF/IL inhibitors, interferon

Contraindications

Condition	Which vaccine(s) should be avoided if this condition is present?
Severe allergic reaction following a previous dose	Any vaccine
History of encephalopathy without identifiable cause following administration of previous dose of pertussis-containing vaccine	DTaP, Tdap
Anaphylaxis when exposed to gelatin or neomycin	MMR, varicella, zoster, IPV
Children or adolescents receiving long-term aspirin therapy	LAIV
Immunodeficiency due to disease (such as HIV), chemotherapy, radiation, immunosuppressive therapy	MMR, varicella, LAIV, zoster

Precautions

Condition	Which vaccine(s) should additional information be obtained if this condition is present?
Hives when eggs are consumed	IIV
Recent receipt of antibody-containing blood products	MMR, Varicella,
History of Arthus-type hypersensitivity	DTaP, DT, dT, Tdap
Need for tuberculin skin testing	MMR
History of Guillian-Barré syndrome within 6 weeks of a previous dose of vaccine.	IIV, LAIV TD, dT, Tdap, DTaP

Patient Case: Pat (continued)
Reviewing a Screening Questionnaire

Pat provides the following information on the screening questionnaire:

1. Are you sick today?	Yes
2. Do you have allergies to medications, food, a vaccine, or latex?	Yes
3. Have you ever had a serious reaction after receiving a vaccine?	Yes
4. Do you have a long-term health problem with heart disease, lung disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia, or other blood disorder?	Yes
5. Do you have cancer, leukemia, HIV/AIDS or other immune system problems?	No
6. In the last 3 months, have you taken any medications that weakens your immune system (e.g., cortisone, prednisone, other steroids, anticancer drugs, or radiation treatments)?	No No
7. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	No
8. Have you received any vaccinations in the past 4 weeks?	No

How would you proceed after reviewing this completed screening form?

Applying Your Knowledge to Practice

- *What additional information would you gather from Pat before administering the vaccines?*
  - *Ask her to explain the current symptoms*
  - *Ask her to specify the allergies to medication, food, or vaccines*
  - *Ask her to describe the reaction after receiving a vaccine*
  - *Ask her what long-term health problems she has*

Patient Case: Pat (continued) Additional Information Gathered

- *Pat has been fighting a cold for a couple of weeks, but her symptoms have been improving over the past several days*
- *Pat is allergic to penicillin*
- *Pat has a history of fainting after receiving shots or getting blood drawn*
- *Pat has a history of heart failure*

Patient Case: Pat (continued)

- *Based on this information, would you administer the vaccines to Pat?*
  - *Yes, it would be appropriate to administer the vaccines because there are no valid contraindications or precautions*
- *Would you administer all of her recommended vaccinations simultaneously?*
  - *According to ACIP, she can receive all of her vaccines simultaneously*

Patients Making Vaccine Decisions

Vaccination Decision-Making Factors

- *Perceived susceptibility to the disease*
- *Perceived seriousness of the disease*
- *Perceived vaccine benefits*
- *Perceived barriers (adverse effects, access, cost, time)*
- *Social influence (e.g., from a pharmacist)*

Pharmacists as Vaccine Advocates

- *Up to 94% of people respond to a pharmacist's recommendation to be vaccinated*
- *People were 74% more likely to be vaccinated if prompted by their pharmacist than if not prompted*
- *No other health care professional is as accessible, especially in rural and other underserved areas*

Informing and Consenting: A Two-Way Street

- *Providing a Vaccine Information Statement to the patient is required by NCVIA for many vaccines; prudent for all*
  - *VISs are available from:*
    - *www.cdc.gov/nip*
    - *www.immunize.org*
- *VIS provides overview of the benefits and risks of vaccination*
- *Obtaining signature from the patient varies with site and local requirements*
  - *Mimic the procedures of local health department*

Misconceptions About Vaccines

- *Diseases were disappearing before vaccines*
- *There is no need to continue vaccinating*
- *Vaccines cause harmful effects*
- *People with disease were vaccinated*
- *Hot lots of vaccines exist*
- *Multiple vaccinations overload the immune system*

http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/

Institute of Medicine Safety Review

- *Vaccines and autism*
- *Thimerosal-containing vaccines and neurodevelopmental disorders*
- *Hepatitis B vaccine and neurological disorders*
- *Vaccines and sudden infant death*
- *Multiple vaccines and immune dysfunction*
- *Influenza and neurological complications*

http://www.iom.edu/Reports.aspx?page=1&Series={6F4ACEDB-41C5-4AC5-BBDE-39D9A343A8D3}

Credible Vaccine Websites

- The Albert B. Sabin Vaccine Organization
- American Academy of Family Physicians
- American Academy of Pediatrics
- American Medical Association
- ASTHO (Association of State and Territorial Health Officials)
- Autism Science Foundation
- Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration
- Emory Vaccine Center
- Families Fighting Flu
- Immunization Action Coalition
- Institute of Medicine
- Institute for Vaccine Safety
- Part of John Hopkins Bloomberg School of Public Health
- Meningitis Angels
- National Center for Immunization and Respiratory Diseases
- Part of Centers for Disease Control and Prevention
- National Network for Immunization Information
- Parents of Kids with Infectious Diseases
- Vaccine Education Center at the Children's Hospital of Philadelphia
- Voices for Vaccines

http://www.vaccinateyourbaby.org/resources/organizations.cfm

Resources About Vaccine Safety

- Centers for Disease Control and Prevention
  - Vaccine safety and adverse events
    - www.cdc.gov/vaccines/vac-gen/safety/default.htm
  - Vaccine safety
    - www.cdc.gov/vaccinesafety/index.html
  - Provider resources for vaccine conversations with parents
    - www.cdc.gov/vaccines/spec-grps/hcp/conv-materials.htm#uvss
- Immunization Action Coalition
  - http://www.immunize.org/safety/
- World Health Organization
  - www.who.int/immunization_safety/en/
- Global Advisory Committee on Vaccine Safety
  - www.who.int/vaccine_safety/en/

Documentation and Record- Keeping

Immunization Records

- *Role of the pharmacist*
  - *Review immunization records*
  - *Compare vaccination history to recommended immunization schedules*
  - *Determine individual's vaccination needs*
  - *Encourage patients to bring the record to every health care visit*
  - *Document any vaccines provided to the patient on the immunization record*
  - *Report to state registries (Immunization Information Systems – IIS)*
- *Immunization records are available from various organizations: APhA-ASP, IAC, health departments, State Department*

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What If Someone Loses an Immunization Record?

- *Ask the patient to look again*
- *Ask previous provider(s), day care, schools — but do not waste too much time*
- *Do not assume events without documentation; vaccinate to be sure*
- *Duplicated doses might mean a sore arm, but that is preferable to being susceptible to fatal diseases*

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Federal Requirements for Documentation

- *National Vaccine Injury Compensation Program (VICP) Act passed in 1986*
- *Required documentation for all vaccines covered by VICP:*
  - *Date vaccine administered*
  - *Vaccine manufacturer*
  - *Vaccine lot number*
  - *Name, address, title of person administering the vaccine*
  - *Date printed on the VIS*
  - *Date the VIS is given to the vaccine recipient or the recipient's legal representative*
- *Signature is not required by federal law*
  - *Verify local or state requirements*

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Perpetual Immunization Logs

- *Pen and paper*
- *Software options (databases)*
  - *Pharmacy profiling software (never purge)*
  - *Comprehensive Clinic Assessment Software Application (CoCASA)*
  - *Electronic medical records (EMR)*
  - *Immunization information systems (formerly known as immunization registries)*
    - *Immunization records should be permanent and easily retrievable*

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Continuity of Care

- *Report to immunization information systems when possible*
  - *Many states have electronic vaccine registries for children and adolescents*
  - *Utilized in quality measures (NCQA, HEDIS)*
  - *Valuable in emergency situations and pandemic outbreaks*
- *Report vaccines to primary care provider*
  - *Avoid patchwork of records*

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Adverse Events Following Vaccination
and
Emergency Preparedness

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Events vs. Reactions

- *Definitions*
  - *Adverse reaction: Caused by vaccine*
  - *Adverse event: Cause or coincidence?*
- *It is often difficult to discern the cause-and-effect relationship (causality)*

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General Rule—Adverse Reactions

- *Inactivated vaccines are expected to commonly produce reactions at the injection site; may be with or without fever*
  - *Inflammatory response to antigen*
- *Live attenuated vaccines are expected to produce a mild form of the natural illness, in the process of replicating, after the incubation period*

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True vs. False Allergy

- *Immediate-type hypersensitivity (typically within minutes to an hour or so)*
- *True (immediate) allergy*
  - *Itching, erythema, hives, urticaria; symptoms progressing toward anaphylaxis*
- *False allergy*
  - *Fever, GI upset, red eyes w/thimerosal (contact lens solutions), neurologic events*

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Vasovagal Syncope

- *A transient loss of consciousness due to withdrawal of sympathetic nervous system tone*
  - *63% occur ≤5 minutes following vaccination*
  - *80% occur within 15 minutes of vaccination*
  - *35% reported in persons 10–18 y/o*
  - *71% reported in women*
  - *14% of episodes result in hospitalization*

Centers for Disease Control and Prevention. General Recommendations on Immunization. MMWR 2011;60(2):12.

Symptoms of Syncope

- *Extreme paleness*
- *Sweating*
- *Coldness of the hands and feet*
- *Nausea*
- *Lightheadedness*
- *Dizziness*
- *Weakness*
- *Visual disturbances*
- *Loss of consciousness*

Immunization Action Coalition. Medical management of vaccine reactions in adult patients.

Syncope

- *What do you do if a patient faints after vaccination?*
  - *Follow your emergency response protocol*
  - *Help the patient to the ground so that he or she does not fall, causing injury*
  - *Lay the patient flat on the ground with feet elevated*
  - *If the patient does not regain consciousness quickly, call 911*

Patient Observation

- *"Although syncopal episodes are uncommon and severe allergic reactions are rare, vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated. If syncope develops, patients should be observed until symptoms resolve."*

Centers for Disease Control and Prevention. General Recommendations on Immunization. MMWR 2011;60(2):12.

Symptoms of Anaphylaxis

- *Sudden or gradual onset of generalized itching*
- *Erythema (redness)*
- *Urticaria (hives)*
- *Angioedema (swelling of the lips, face, or throat)*
- *Severe bronchospasm (wheezing)*
- *Shortness of breath*
- *Abdominal cramping*
- *Shock*
- *Cardiovascular collapse*

Immunization Action Coalition. Medical management of vaccine reactions in adult patients.

Patient Case: Helen

- *You appropriately screen Helen, a 55 y/o patient, during an immunization clinic. Helen does not have any contraindications to influenza vaccination; however, she has never received a previous dose of inactivated influenza vaccine. After administering the vaccine, you request that Helen remain in the pharmacy for 20 minutes. Approximately 5 minutes later, Helen returns to the administration area stating that she does not feel very well and would like a drink of water.*
- *What do you do?*

Patient Case: Helen (continued)

- *Over the next few minutes, Helen begins to complain of feeling very hot and starts to complain of shortness of breath.*
- *What do you do?*

Patient Case: Helen (continued)

- *Next, Helen's respirations become very labored and audible wheezes are observed.*
- *What do you do?*

Patient Case: Helen (continued)

- *Helen's breathing initially responds to the epinephrine; however, she begins to wheeze and continues to have shortness of breath.*
- *What do you do?*

Epinephrine

- *Epinephrine doses (based on 1:1,000 w/v, 1 mg/mL)*
  - *Dosing by body weight is preferred*
  - *0.01 mL/kg/dose (max of 0.5 mg per dose)*
- *Repeat epinephrine, if needed, as outlined in your protocol*
- *IM is more prompt than SC*
- *β-adrenergic blockers may antagonize epinephrine; may require higher epinephrine dose*

Epinephrine

- *Never vaccinate if epinephrine is unavailable or expired*
- *Must have multiple doses readily available*
- *Considerations for dosage forms*
  - *1 mg/mL ampule*
  - *Epinephrine autoinjectors*
    - *EpiPen and EpiPen Jr.*
    - *Auvi-Q*
    - *0.15 mg and 0.3mg dose available*

Acute Reactions

- *Allow for fainting without injury, plus access to hard surface if CPR is needed*
- *Be prepared for anaphylaxis*
  - *It is extremely rare and potentially fatal, but usually reversible with immediate recognition and treatment*
- *Remind patients and caregivers to report any adverse events that happen at home*
  - *Submit these events to VAERS*

Emergency Response Summary

- *Screen patient appropriately before vaccination*
- *Observe patient for a suitable period of time after vaccination*
  - *ACIP recommends that patients be observed for 15 minutes postvaccination*
- *Follow the emergency plan if need arises*
  - *911 (EMS) + epinephrine + CPR/BCLS*
- *Mimic safeguards used by local health department and home health care givers*

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Emergency Response Reminders

- *Have a plan and practice it!*
- *Train all staff*
- *Have a sufficient supply of epinephrine*
- *Stay calm*

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Questions?

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Vaccine Administration Technique

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Injection Technique Video
Click here to watch the video

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General Guidelines for Vaccine Administration

- *Wash hands*
- *Check expiration dates*
- *Confirm right vaccine*
  - *Be careful about look-alike/sound-alike names*
  - *Be careful about look-alike packaging*
- *Maintain sterility while preparing the dose*
- *Draw up dose using appropriate technique*
- *Check for air bubbles*
- *Position sharps container within reach*
- *Never take your eyes off the needle*
- *Activate safety device immediately*
- *Dispose of needle properly*
- *Remove gloves and wash hands*

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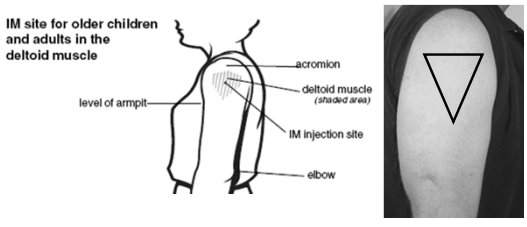
Preparing Vaccine Doses

- *Remove the protective cap*
- *Swab the top of the vial with alcohol*
- *Pull back the plunger to draw air into the syringe equal to the designated volume for injection*
- *Insert the syringe into the vial and inject the air to displace the volume needing to be withdrawn*
- *Turn the vial and syringe upside down and withdraw the dose*
- *Ensure that large air bubbles do not exist*

Intramuscular Injections

- *Site*
  - *Infants*
    - *Anterolateral thigh*
    - *Not taught in this course*
  - *Children >3 y/o and adults*
    - *Deltoid muscle*

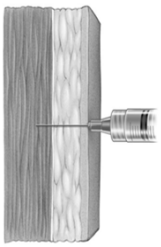
Deltoid Muscle



Intramuscular Injection

Weight	Needle Size
Men and women <60 kg (<130 lb)	1 inch
Women 60–90 kg (130–200 lb) Men 60–118 kg (130–260 lb)	1–1½ inches
Women >90 kg (>200 lb) Men >118 kg (>260 lb)	1½ inches
Children (deltoid)	⅝–1¼ inches

22–25 gauge
Insert at 90° angle



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Intramuscular Injection

- Uncover area
- Wipe with alcohol and let alcohol dry
- Tell patient to relax
- Insert needle at 90° to skin in a smooth controlled motion while bracing against the arm
- Depress the plunger
- Withdraw the needle swiftly
- Activate safety device immediately
- Dispose of syringe in sharps container
- Press cotton or gauze and tape to patient
- Wash hands

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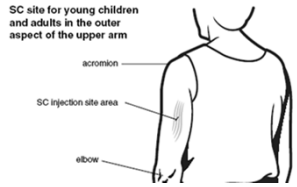
Subcutaneous Injection

- Site
  - Children >3 y/o and adults
    - Outer aspect of upper arm (posterolateral)



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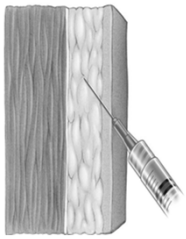
Subcutaneous Injection

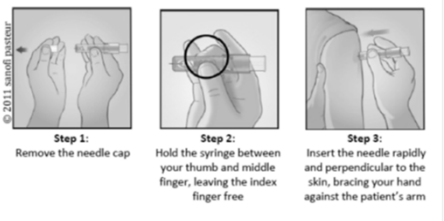
- *⅝ inch*
- *23–25 gauge*
- *Insert at 45˚ angle*



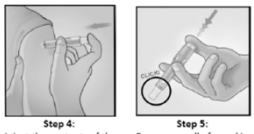
Subcutaneous Injection

- *Uncover area*
- *Wipe with alcohol and let alcohol dry*
- *Tell patient to relax*
- *Pinch fold of skin*
- *Insert needle at 45˚ angle to skin while bracing against the arm.*
- *Depress the plunger*
- *Withdraw needle swiftly*
- *Activate safety device immediately*
- *Dispose of syringe in sharps container*
- *Press cotton or gauze and tape to patient*
- *Wash hands*

Intradermal Administration of Fluzone ID



Intradermal Administration of Fluzone ID



Step 4: Inject the contents of the syringe with your index finger

Step 5: Remove needle from skin and activate the needle shield by pushing firmly on the plunger until you hear a click

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Clinical Pearls for Injection Administration

- *Patient should be sitting*
  - *May want to use a chair with arms*
  - *Have adequate space to lay person down if necessary*
- *Expect bleeding*
  - *Patient can hold cotton swab until bandage placed*
- *Hitting bone does not hurt patient*
- *Avoid (when possible)*
  - *Scars*
  - *Tattoos*
  - *Moles*
- *Do not aspirate syringe in patient*

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Safeguarding Against Needlesticks

"Following injection, activate the safety device and deposit it in the sharps container.

Do not take your eyes off the needle!"

Stephan Foster, Memphis, TN

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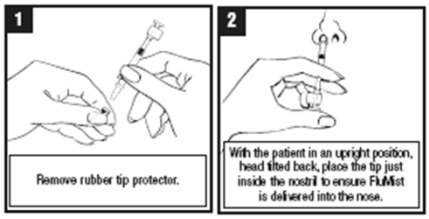
Intranasal Vaccine



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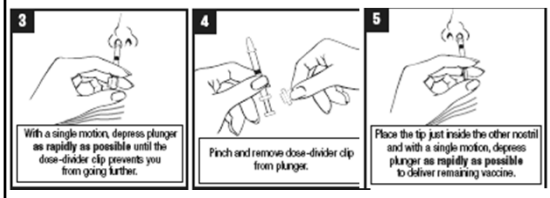
FluMist [package insert].

Intranasal Vaccine (continued)



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FluMist [package insert].

Clinical Pearls for Intranasal Administration of LAIV

- *Provide patient with a tissue prior to administration*
- *Instruct patient not to sniff or inhale spray*
- *Insert tip of the sprayer just inside the nose and depress the plunger to spray half the dose into the first nostril*
- *Remove the dose-divider clip; administer second dose in the other nostril*
- *No need to repeat if sneezing or coughing occur*

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Questions?

Directions: Skills Assessment

- *You need to find a partner*
- *You will be giving and receiving three injections (2 IM and 1 SC) of normal saline*
- *Draw up three doses of saline in the appropriate syringes*

One of the faculty members must see all three injections or they do not count—you will have to repeat them